EXHIBIT K

US005449373A

United States Patent [19]

Pinchasik et al.

[11] Patent Number: 5,449,373

[45] Date of Patent: Sep. 12, 1995

[54] **ARTICULATED STENT**

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[73] Assignee: Medinol Ltd., Ramat Hasharon, Israel

[21] Appl. No.: 213,272

[22] Filed: Mar. 17, 1994

[51] Int. Cl.[6] A61M 5/00; A61F 2/02

[52] U.S. Cl. 606/198; 623/1; 623/12

[58] Field of Search 623/1, 11, 12; 606/108, 606/191-195, 198, 200; 604/8

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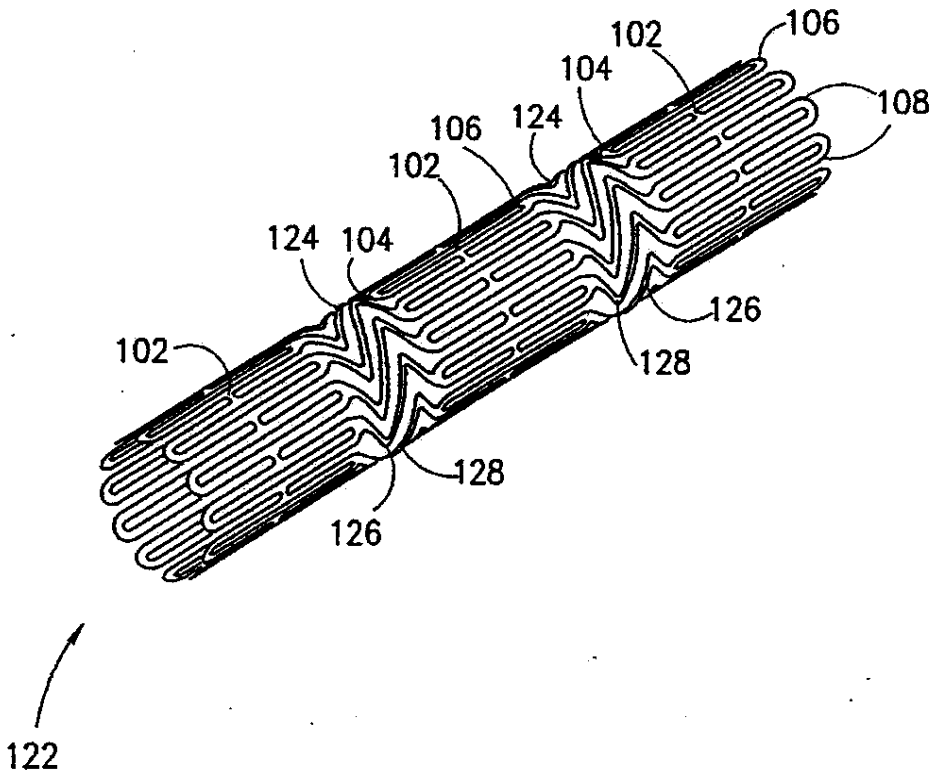
Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—William Lewis
Attorney, Agent, or Firm—Skjerven, Morrill, MacPherson, Franklin & Friel

[57] ABSTRACT

An articulated stent for delivering through a bodily conduit, for example, a peripheral or coronary artery, which has one or more curved portions and for implantation therein. The articulated stent includes at least two substantially rigid segments and a flexible connector for connecting adjacent segments. The connector assumes a cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

6 Claims, 5 Drawing Sheets



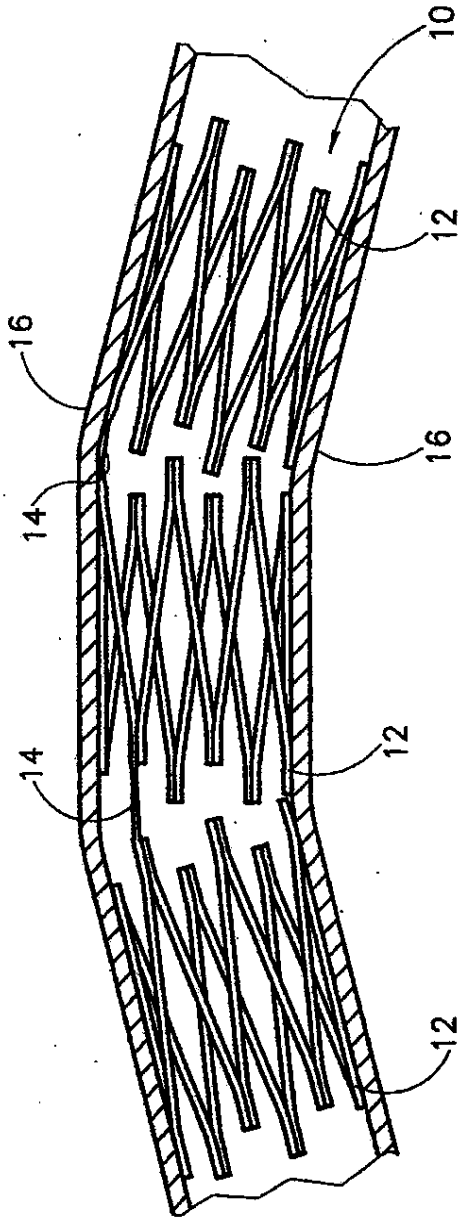


FIG. 1
PRIOR ART

FIG.2A

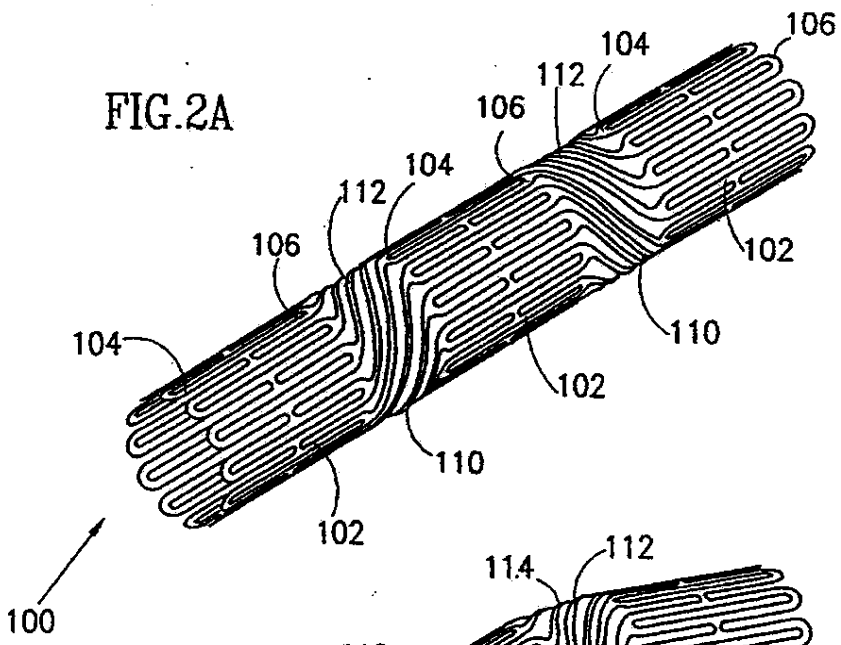


FIG.2B

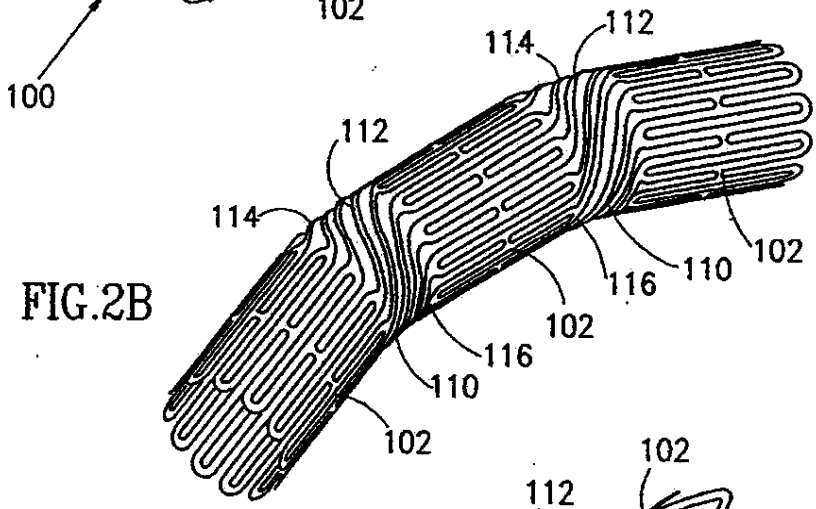
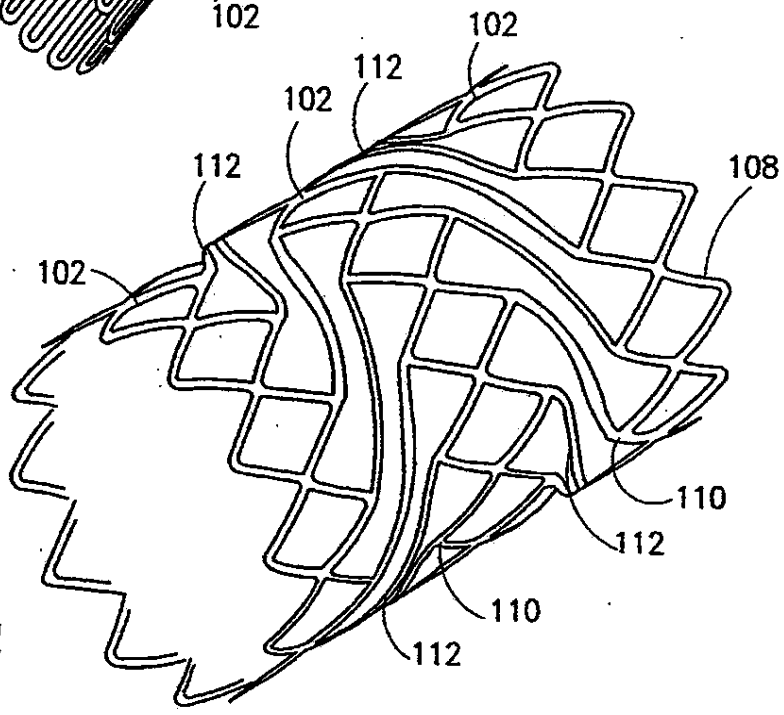
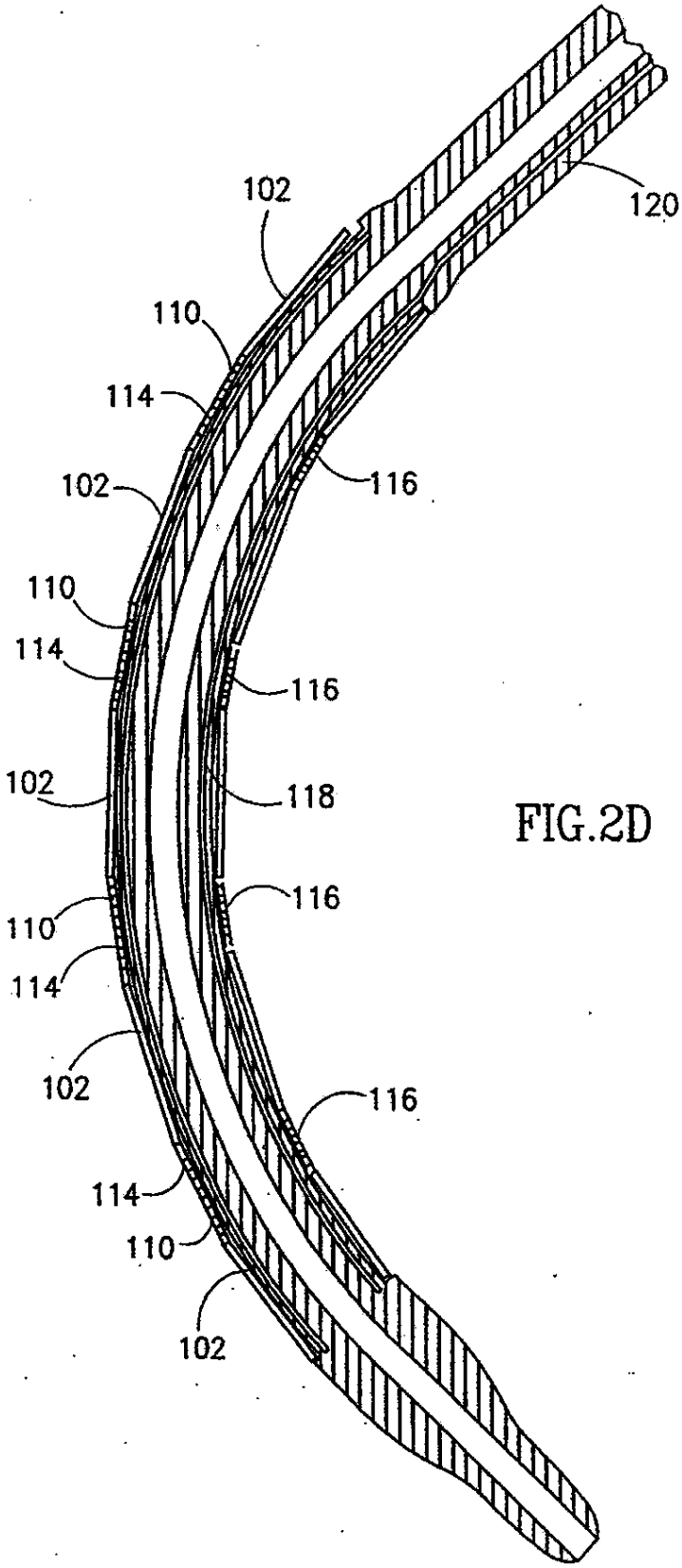


FIG.2C




102
120
110
114
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114
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102

FIG.2D

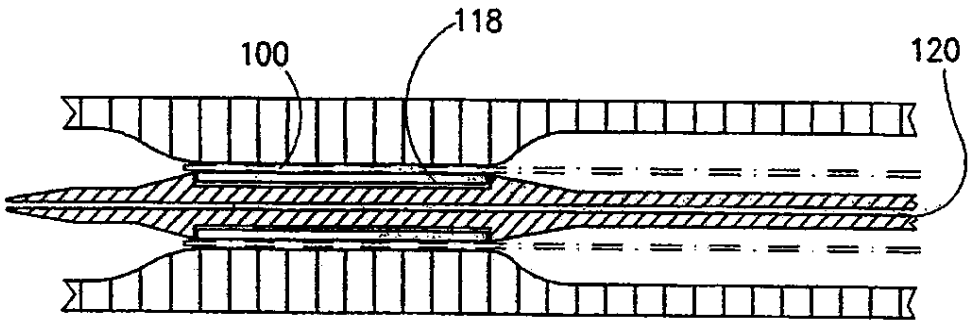


FIG.2E

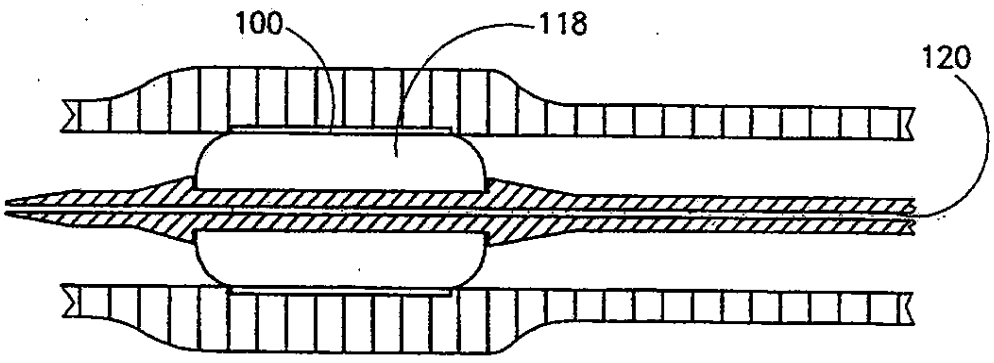


FIG.2F

FIG.3A

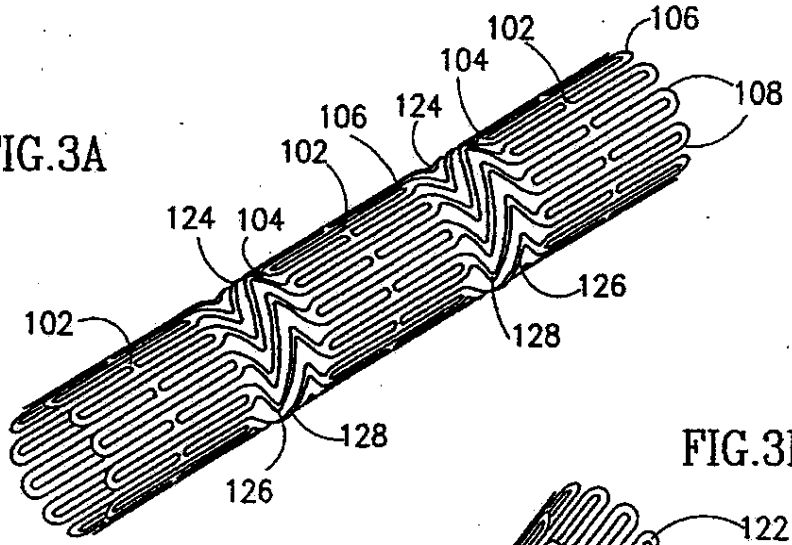


FIG.3B

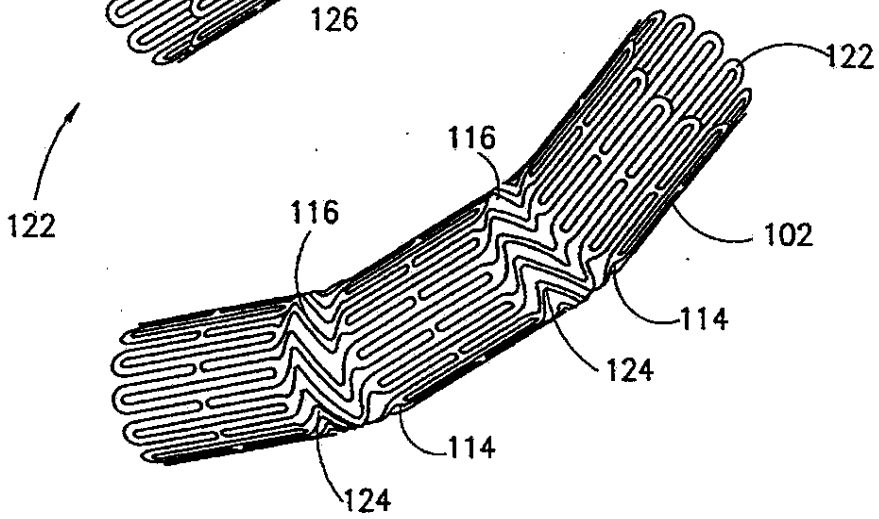
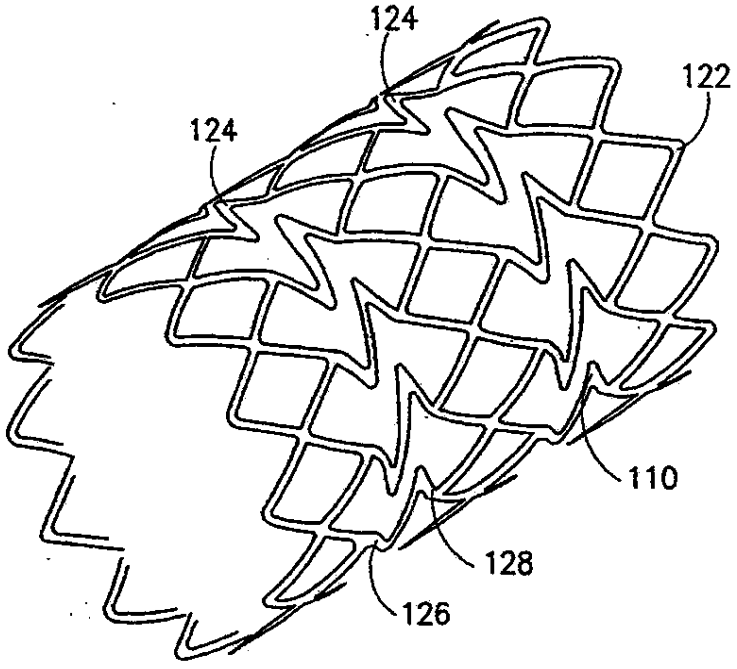


FIG.3C



ARTICULATED STENT

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to stents which are implanted as part of a balloon angioplasty procedure within a bodily conduit of a living animal or a human to maintain patency. In particular, the present invention relates to articulated intravascular stents for delivery through or implantation in a blood vessel having a curved portion.

Intravascular stents having a constricted diameter for delivery through a blood vessel and an expanded diameter for applying a radially outwardly extending force for supporting the blood vessel are known in the art. Articulated intravascular stents for either delivery through a curved blood vessel or implanted therein are also known in the art.

Self-expandable articulated stents are described, for example, in U.S. Pat. No. 5,104,404 entitled "Articulated Stent" to Wolff. Balloon expandable articulated stents are commercially available under the trade name Palmaz-Schatz Balloon-Expandable Stents from Johnson & Johnson Intervention Systems Co.

A prior art self-expandable articulated intravascular stent **10** deployed in a curved blood vessel **16** is now described with reference to FIG. **1** which is, in actual fact, FIG. **2** of the above referenced U.S. Pat. No. 5,104,404. Stent **10** is made up of a number of individual segments **12** articulated by hinges **14** connected at each end to segments **12**. Stent **10** is preferably fabricated from memory shape material, for example, nitinol, and as such is self expandable after delivery from a delivery system described in U.S. Pat. No. 4,830,003 to Wolff et al. However, these prior art articulated intravascular stents suffer from a number of disadvantages both during delivery through a curved blood vessel and when implanted therein as will now described.

The delivery of stent **10** through curved blood vessel **16** is more complicated than the delivery of a non-articulated stent in that stent **10** has to be angularly oriented such that its hinges **14** are located towards the convex portion of blood vessel **16** so that stent **10** can be flexed inward. In the present example, it will be noted that hinges **14** are located on the same side of segments **12** because blood vessel **16** has only a simple curve in one plane. It can be readily appreciated that delivery of stents through blood vessels which have one or more curved portions which are not in the same plane is even more complicated and generally requires specially constructed stents.

Even when implanted in a curved blood vessel **16**, stents **10** are shown to be lacking in that the gaps between segments **12** render the curved portion of blood vessel **16** without support. Furthermore, the gaps at the convex portion of blood vessel **16** are substantially greater than the gaps at the concave portion thereof, thereby inducing non-uniform and therefore undesirable stresses on blood vessel **16**.

Therefore, it would be highly desirable to have an articulated stent which does not require any particular angular orientation when being delivered through a curved bodily conduit and provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted.

It would also be highly desirable the structure of a stent does not depend on the particular orientations of curved portions of a blood vessel.

SUMMARY OF THE INVENTION

The object of the present invention is for an articulated stent which can be delivered through a curved bodily conduit using a routine medical procedure and a conventional stent delivery system. Furthermore, the stent provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted. Still further, the structure of a stent and its support of a bodily conduit do not depend on the orientations of the curved portions **6**f the conduit.

The objective of the present invention is achieved by an articulated stent, comprising: (a) at least two substantially rigid segments; and (b) a flexible connector for connecting adjacent segments, wherein the connector assumes a substantially cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

After expansion, the rigid segments of the stent preferably present a fine diamond shaped mesh having 1 mm long sides to provide continuous and uniform support for straight portions of a bodily conduit.

The connectors can be implemented as a plurality of substantially helical links connecting adjacent segments. Alternatively, the connectors can be implemented as links each having at least one kink. The connectors typically have between 8–24 links to provide continuous and uniform support for both straight and curved portions of a bodily conduit.

The stents have constricted diameters for intraluminal delivery and are then deformed, by the inflation of a balloon forming part of their catheter delivery system, to expanded diameters for applying radially outwardly extending forces for supporting the lumen of bodily conduits. The constricted and expanded diameters of the stents typically fall in the ranges of 1.0–3.5 mm and 3.5–10.0 mm, respectively.

The stents are preferably fabricated from low memory, more plastic than elastic, bio-compatible materials, for example, stainless steel 316L, gold, tantalum, etc. which enables them to be plastically deformed from their constricted diameters to their expanded diameters.

A typical stent for implantation in a human coronary artery is 9–21 mm long comprising three to seven 2.2 mm long stent segments connected by two to six 1 mm long connectors such that the ends of the stent subtend between a 45° to 135° angle at a radius of curvature of approximately 9 mm when flexed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. **1** shows a close-up view of a prior art articulated stent of deployed in a curved blood vessel;

FIGS. **2***a* and **2***b* show a preferred embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation;

FIG. **2***c* shows the expanded stent of FIG. **2** after plastic deformation;

FIG. **2***d* shows the stent of FIG. **2** mounted on a catheter in its flexed state;

FIGS. 2*e* and 2*f* show the stent of FIG. 2 before and after expansion by a balloon forming part of its catheter delivery system;

FIGS. 3*a* and 3*b* show a second embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation; and

FIG. 3*c* shows the expanded stent of FIG. 3 after plastic deformation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an articulated stent for delivering through a curved bodily conduit, for example, a peripheral or coronary artery of a living animal or a human and implantation therein as part of a balloon angioplasty procedure to maintain patency.

The principles and operation of the articulated stent of the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, FIGS. 2*a*–2*c* show an articulated stent, generally designated **100**, constructed and operative according to the teachings of the present invention, generally comprising a number of substantially rigid segments **102** connected by connectors **110**.

Segments **102** are preferably made up to present a fine diamond mesh of interconnected diamond shaped cells **108** having 1 mm sides on expansion as best seen in FIG. 2c. Depending on the intended diameter of stent **100**, segments **102** typically comprise between 8–24 diamond shaped cells **108**.

Connectors **110** comprise links **112** connecting a front end **104** to a tail end **106** of adjacent segments **102**. Links **112** preferably extend in a substantially helical fashion between apexes of diamond shaped cells **108** at front and rear ends **104** and **106** of adjacent segments **102** such that the number of links **112** equals the number of cells **108**. Links **112** are preferably evenly deployed around perimeters of segments **102** such that connectors **110** can be equally flexed in any direction and to provide continuous and uniform support to both straight and curved portions of a bodily conduit.

Alternate connectors **110** at front and rear ends **104** and **106**, respectively, of a segment **102** preferably have links **112** wound in clockwise and counter clockwise directions. Alternately winding connectors **110** ensures that the rotational displacement of links **112** and adjacent segments **102** relative to the walls of a blood vessel and more importantly the balloon of its delivery system is minimized when stent **100** is expanded.

It is particular feature of the present invention that connectors **110** have a generally cylindrical configuration when stent **100** is relaxed as best seen in FIG. 2*a* and a differentially stretched and compressed curved configuration when stent **100** is flexed as best seen in FIG. 2*b*. The flexed configuration is brought about by two relatively opposing displacements of links **112**. First, the differential stretching of connectors **110** occurs at the convex portion thereof denoted **114** by links **112** being displaced away from one another. Second, the differential compressing of connectors **110** occurs at the concave portion thereof denoted **116** by links **112** being displaced towards one another.

Stent **100** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 2*a* and 2*b* and an expanded diameter as shown in FIG. 2*c* for supporting a bodily conduit. Stent **100** is preferably fabricated from low memory, more plastic than elastic, bio-compatible material, for example, stainless steel 316L, gold, tantalum, etc. which enables it to be plastically deformed from its constricted diameter to its expanded diameter. The constricted and expanded diameters of stent **100** typically fall in the ranges of 1.0–3.5 mm and 3.5–10.0 mm, respectively.

With reference now to FIGS. 2*d*–2*f*, stent **100** is shown overlying a balloon **118** forming part of its catheter delivery system **120**. Stent **100** is mounted on its catheter delivery system **120** in its constricted diameter state shown in FIG. 2*e* for plastic deformation through inflation of balloon **118** to its expanded diameter shown in FIG. 2*f* for supporting the walls of a bodily conduit. An exemplary stent for implantation in a human coronary artery, is typically 15 mm long made up of five 2.2 mm long segments **102** connected by four 1 mm long connectors **110** and capable of flexion such that its ends subtend a 90° angle at a radius of curvature of approximately 9 mm.

The delivery of articulated stent **100** is considerably simpler than the delivery of prior art articulated stent **10** because stent **100** is equally flexible in all direction and therefore does not require a dedicated angular orientation to pass a particular curved portion. This advantage is particularly important for delivery through blood vessels having multiple curved portions. It is a further advantage of stent **100** over prior art stents **10**, that stent **100** provides continuous and uniform support along the entire length of a blood vessel by means of segments **102** and unflexed connectors **110** supporting straight portions thereof while connector portions **114** and **116** supporting convex and concave curved portions thereof, respectively.

With reference now to FIGS. 3*a* and 3*b*, an articulated stent **122** is shown in which connectors **124** comprise links **126** having one or more kinks **128**. The design of connectors **124** is preferred to that of connector **110** because stent **100** may have a tendency to rupture balloon **118** due to two reasons. First, links **112** overlying the convex portion of balloon **118** have a tendency to be biased inward when stent **100** is flexed. Second, segments **102** display a rotational displacement relative to balloon **118** when stent **100** is expanded.

In this case, the differentially stretched and compressed curved configuration of connector **124** is brought about by two relatively opposing displacements of links **112** as before except that the differential stretching of connectors **124** at convex portion **114** occurs by kinks **128** being somewhat straightened out while the differential compressing of connectors **124** at concave portion **116** occurs by kinks **128** being more acutely bent.

In a similar fashion to stent **100**, stent **122** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 3*a* and 3*b* and an expanded diameter as shown in FIG. 3*c* for supporting a bodily conduit when implanted therein.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

What is claimed is:

1. An articulated stent, comprising:

(a) at least two substantially rigid segments having a plurality of connected cells each having apices, wherein, upon expansion, each of said rigid seg-

ments presents a substantially cylindrical diamond mesh; and

(b) a flexible connector, comprising a plurality of flexible links

wherein each of said flexible links connects apices of adjacent cells on adjacent rigid segments;

each of said flexible links includes a plurality of portion with each pair of neighboring portions having an area of inflection therebetween, and during expansion of said stent, said area of inflection remains inflected.

2. The stent as in claim 1, wherein said plurality of links includes between 8–24 links.

3. The stent as in claim 1 made from bio-compatible material capable of a more plastic than elastic deformation.

4. The stent as in claim 3, wherein said material is stainless steel.

5. The stent as in claim 3, wherein said material is gold.

6. The stent as in claim 3, wherein said material is tantalum.

* * * * *

EXHIBIT L

REDACTED

EXHIBIT M

US006348065B1

(12) **United States Patent**
Brown et al.

(10) **Patent No.: US 6,348,065 B1**
(45) **Date of Patent: *Feb. 19, 2002**

(54) **LONGITUDINALLY FLEXIBLE EXPANDABLE STENT**

(75) Inventors: **Brian J. Brown**, Hanover; **Michael L. Davis**, Shorewood, both of MN (US)

(73) Assignee: **Scimed Life Systems, Inc.**, Maple Grove, MN (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/122,431**

(22) Filed: **Jul. 24, 1998**

Related U.S. Application Data

(63) Continuation of application No. 08/511,076, filed on Aug. 3, 1995, which is a continuation-in-part of application No. 08/396,569, filed on Mar. 1, 1995, now abandoned.

(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/1.16**; 606/198; 623/1.18

(58) **Field of Search** 623/1.15, 1.16, 623/1.17, 1.18, 1.19; 606/195, 198

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Primary Examiner—Paul B. Prebilic
(74) *Attorney, Agent, or Firm*—Vidas, Arrett & Steinkraus

(57) **ABSTRACT**

The invention provides a tubular expandable stent including a plurality of cylindrically shaped open cylindrical segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating flexible pattern of interconnected substantially parallel struts with pairs thereof having alternating interconnecting end portions to define the periphery of the expandable stent segment, and in which the connected end portions of paired struts in each segment, before the stent is expanded, are positioned substantially opposite to connected end portions of paired struts in adjacent segments.

45 Claims, 5 Drawing Sheets

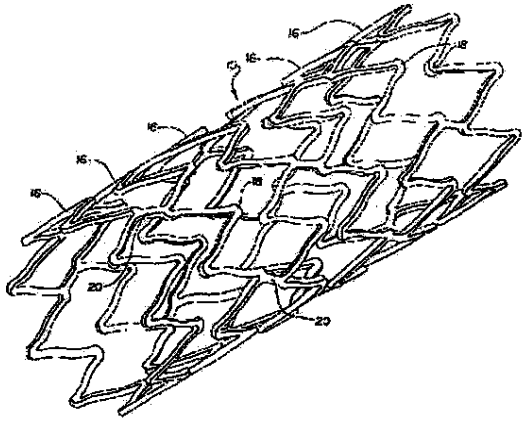

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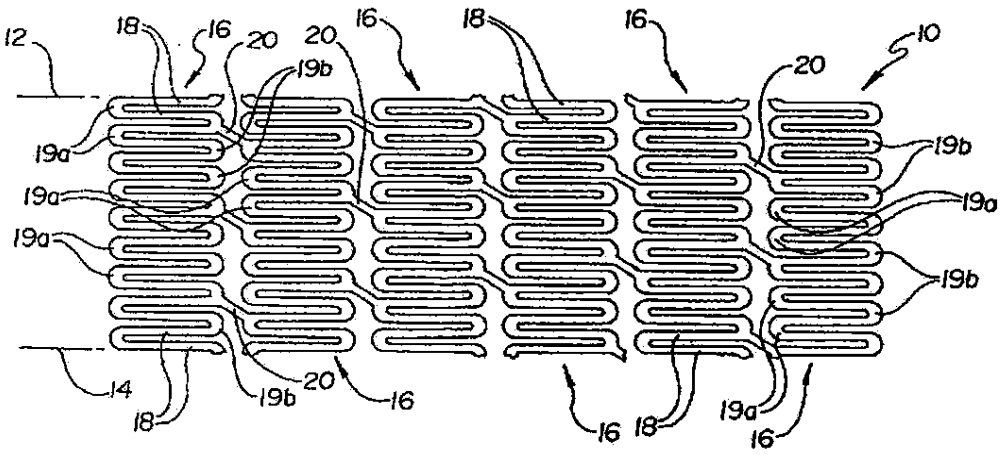
Fig. 1


12
18
16
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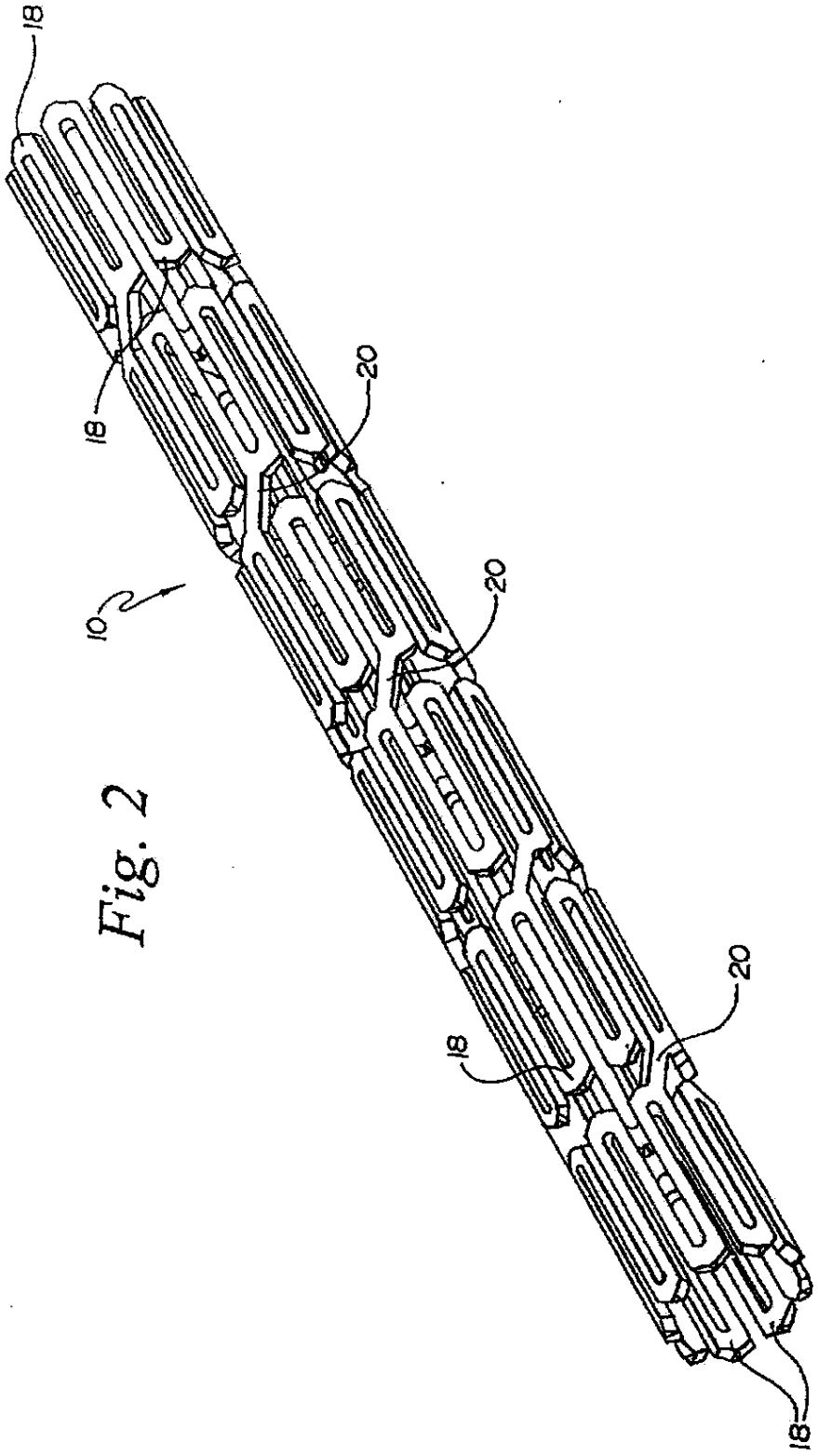


Fig. 2

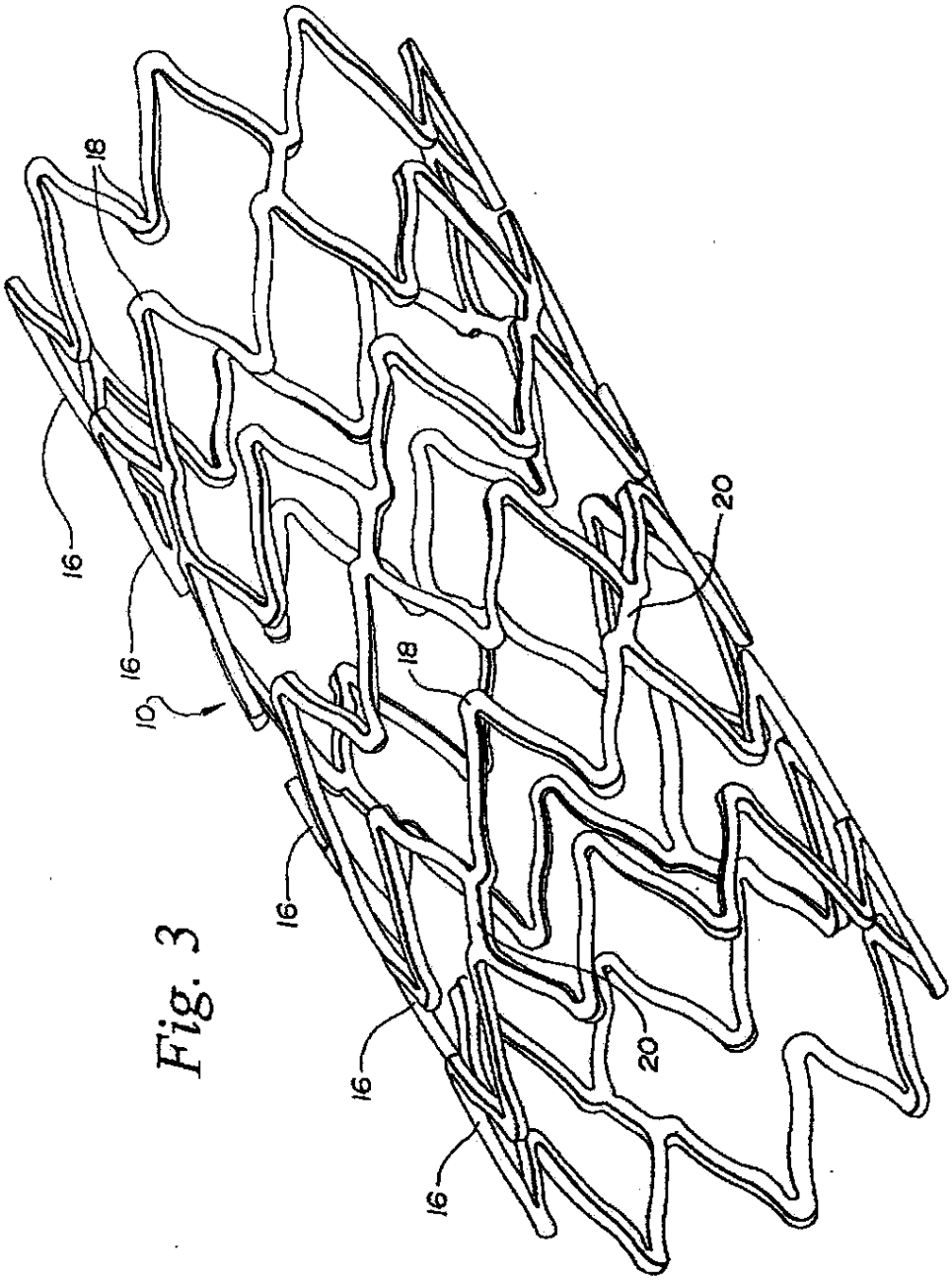
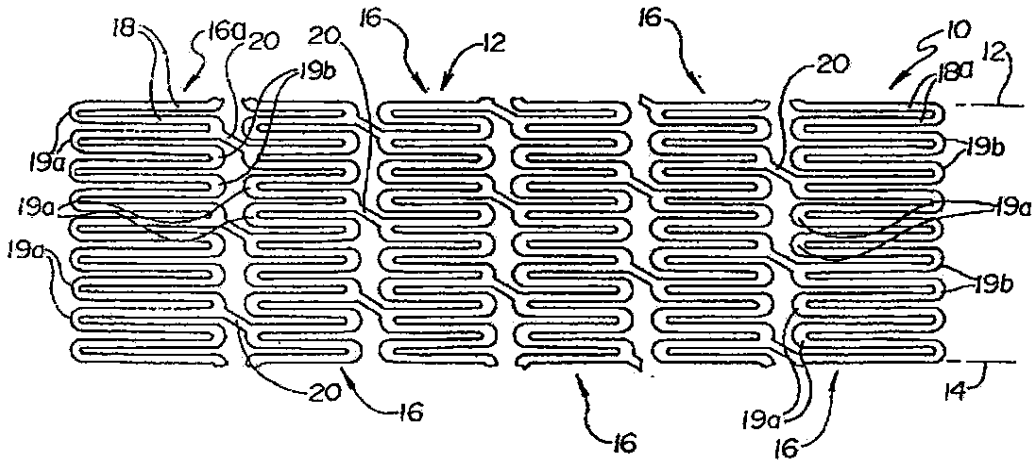


Fig. 3

Fig. 4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16a
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18a
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19b
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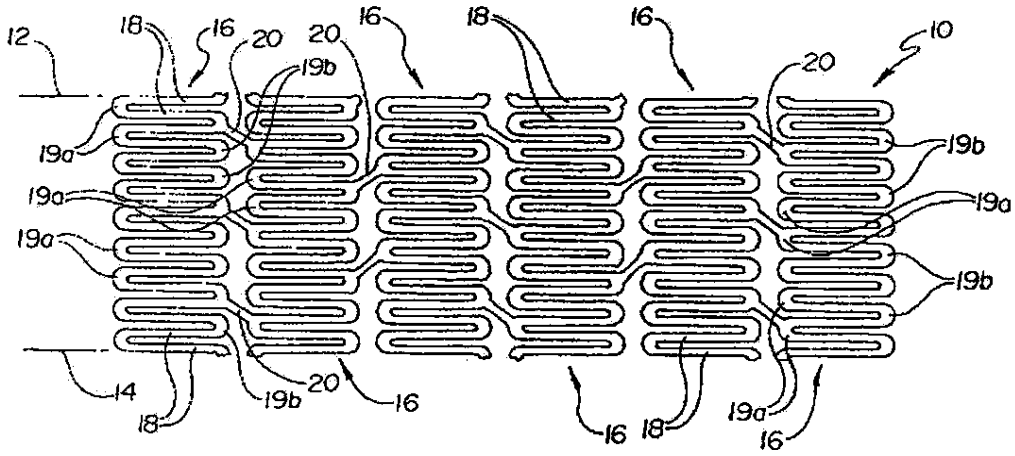
19b
20
16
16
19a
16
14

Fig. 5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19b
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16
16
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19a
16

LONGITUDINALLY FLEXIBLE EXPANDABLE STENT

This application is a continuation of Ser. No. 08/511,076 filed Aug. 3, 1995 which is a continuation-in-part of Ser. No. 08/396,569 filed Mar. 1, 1995 and now abandoned.

FIELD OF THE INVENTION

This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular expandable stent of improved longitudinal flexibility.

BACKGROUND OF THE INVENTION

Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

An example of the latter type is shown in U.S. Pat. No. 4,733,665 to Palmaz, which issued Mar. 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

A type of self-expanding stent is described in U.S. Pat. No. 4,503,569 to Dotter which issued Mar. 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

This invention is directed to stents of all these types when configured so as to be longitudinally flexible as described in detail hereinbelow. Flexibility is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known n the prior art. Examples are shown in U.S. Pat. No. 4,856,516 to Hillstead; U.S. Pat. No. 5,104,404 to Wolff; U.S. Pat. No. 4,994,071 to MacGregor; U.S. Pat. No. 5,102,417 to Palmaz; U.S. Pat. No. 5,195,984 to Schatz; U.S. Pat. No. 5,135,536 to Hillstead; U.S. Pat. No. 5,354,309 to Shepp-Pesch et al.; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

Generally speaking, these kinds of stents are articulated and are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact or on the outside of a bend the segments can move away from each other, leaving large gaps. This can lead to improper vessel support, vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross for devices to be installed through already implanted devices and to unsupported regions of vessel.

A diamond configuration with diagonal connections between each and every diamond of each segment is also known but such closed configurations lack flexibility.

It is an object of this invention to provide a longitudinally flexible stent of open configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally) in the stent body segments thereof rather than in flexible joints between the segments.

SUMMARY OF THE INVENTION

To this end, the invention provides a tubular expandable stent, comprising: a plurality of cylindrical shaped open cylindrical segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating flexible pattern of interconnected substantially parallel struts with pairs thereof having alternating interconnecting end portions to define the periphery of the expandable stent segment, and in which the connected end portions of paired struts in each segment, before the stent is expanded, are positioned substantially opposite to connected end portions of paired struts in adjacent segments. The segments are interconnected by a plurality of interconnecting elements extending from some of the connected end portions on one segment to some of the connected end portions on adjacent segments in such a manner that there are three or more legs between points of connection from one side of each segment to its other side. Additionally, the connecting elements extend angularly from connecting end portion of one segment to connecting end portion of an adjacent segment, not to an opposite connecting end portion on an adjacent segment, whereby upon expansion of the stent the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate flexing of the stent within paired struts without interference between adjacent segments, rather than by means of articulating flexible connectors between segments. As a result, the connectors between the segments are not intended to flex or bend under normal use.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows a flat view of an unexpanded stent configuration according to the invention.

FIG. 2 shows the pattern of FIG. 1 in a tubular, unexpanded stent.

FIG. 3 shows an expanded stent of the configuration shown in FIG. 1.

FIG. 4 shows a flat view of an alternate unexpanded stent configuration according to the invention.

FIG. 5 shows a flat view of an alternative unexpanded stent configuration according to the invention.

BEST MODE DESCRIPTION OF THE INVENTION

Turning to the Figures, FIG. 1 and FIG. 2 show a fragmentary flat view of an unexpanded stent configuration and the actual tubular stent (unexpanded), respectively. That is, the stent is shown for clarity in FIG. 1 in the flat and may be made from a flat pattern 10 (FIG. 1) which is formed into a tubular shape by rolling the pattern so as to bring edges 12 and 14 together (FIG. 1). The edges may then joined as by welding or the like to provide a configuration such as that shown in FIG. 2.

The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 16, each of which is formed in an undulating flexible pattern

of substantially parallel struts **18**. Pairs of struts are interconnected at alternating end portions **19***a* and **19***b*. As is seen in FIG. **1**, the interconnecting end portions **19***b* of one segment are positioned opposite interconnecting end portions **19***a* of adjacent segments. The end portions as shown are generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form **10** is formed into an unexpanded tube as shown in FIG. **2**, the segments are cylindrical but the end portions **19** of adjacent segments remain in an opposed position relative to each other.

A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate configuration.

Interconnecting elements **20** extend from one end portion **19** of one segment **16** to another end portion **19** of another adjacent segment **16** but not to an oppositely positioned end portion **19** of an adjacent segment **16**. There are at least three struts included between the points on each side of a segment **16** at which an interconnecting element **20** contacts an end portion **19**. This results in the interconnecting elements **20** extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements **20** are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upwardly in one case and downwardly in another, as shown in FIG. **5** although all connecting elements between any pair of segments are substantially parallel. FIG. **1**, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

As a result of this angular extension of the interconnecting elements **20** between adjacent segments and loops, upon expansion of the stent as seen in FIG. **3**, the closest adjacent end portions **19** between segments **16** are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments, i.e., pinching.

The number of interconnecting elements **20** may vary depending on circumstances in any particular instance. Three per segment are satisfactory for the configuration shown and at least three will be used typically.

The alternate design shown in FIG. **4** includes longer struts **18***a* in the two end segments **16***a* than in the intermediate segments **16**. This allows the end segments (**16***a*) to have less compression resistance than the intermediate segments (**16**), providing a more gradual transition from the native vessel to the support structure of the stent. Otherwise, the configuration is the same as that shown in FIG. **1**.

As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may be of shape memory alloy such as Nitinol or the like, etc.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A tubular, flexible, self-expandable stent comprising:

1) a plurality of cylindrically shaped segments which are interconnected,

one of the cylindrically shaped segments being an intermediate cylindrically shaped segment having a proximal end and a distal end,

one of the cylindrically shaped segments being a proximal cylindrically shaped segment having a proximal end and a distal end located adjacent the proximal end of the intermediate cylindrically shaped segment and

one of the cylindrically shaped segments being a distal cylindrically shaped segment having a distal end and a proximal end located adjacent the distal end of the intermediate cylindrically shaped segment,

each cylindrically shaped segment being defined by an undulating pattern of interconnected struts, each strut having a proximal end and a distal end, each strut adjacent a first strut and a second strut, the strut and the first strut interconnected only at their distal ends, the strut and the second strut interconnected only at their proximal ends, and

2) a plurality of interconnecting elements including proximal interconnecting elements and distal interconnecting elements, each interconnecting element having a proximal end and a distal end, the proximal end of the interconnecting element circumferentially and longitudinally offset from the distal end of the interconnecting element, the interconnecting elements shorter in length than the cylindrically shaped segments,

each proximal interconnecting element extending proximally from an interconnected proximal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected distal end of adjacent struts on the proximal cylindrically shaped segment,

each distal interconnecting element extending distally from an interconnected distal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected proximal end of adjacent struts on the distal cylindrically shaped segment,

the interconnecting elements extending at an oblique angle relative to the longitudinal axis, a minimum length pathway of at least three interconnected circumferentially adjacent struts on the intermediate cylindrically shaped segment extending between the distal ends of the proximal interconnecting elements and the proximal ends of the distal interconnecting elements,

wherein flexing of the stent occurs substantially in the cylindrically shaped segments.

2. The stent of claim **1** formed of a shape memory metal.

3. The stent of claim **2** formed of nitinol.

4. The stent of claim **1** wherein each interconnecting element extends from a side of an interconnected end of adjacent struts on one cylindrically shaped segment to a side of an interconnected end of adjacent struts on an adjacent cylindrically shaped segment.

5. The stent of claim **1** wherein circumferentially adjacent interconnecting elements are separated by six struts.

6. The stent of claim **1** wherein there are at least three interconnecting elements extending between any two adjacent cylindrically shaped segments.

7. The stent of claim 1 constructed and arranged such that upon expansion of the stent, connected ends of adjacent struts in the proximal cylindrically shaped segment are circumferentially displaced relative to connected ends of adjacent struts in the intermediate cylindrically shaped segment and connected ends of adjacent struts in the intermediate cylindrically shaped segment are circumferentially displaced relative to connected ends of adjacent struts in the distal cylindrically shaped segment to accommodate longitudinal flexing of the stent within the cylindrically shaped segments and without interference between adjacent cylindrically shaped segments.

8. A tubular, flexible, self-expandable stent made of nitinol, the stent comprising:

1) a plurality of cylindrically shaped segments which are interconnected,

one of the cylindrically shaped segments being an intermediate cylindrically shaped segment having a proximal end and a distal end,

one of the cylindrically shaped segments being a proximal cylindrically shaped segment having a proximal end and a distal end located adjacent the proximal end of the intermediate cylindrically shaped segment and

one of the cylindrically shaped segments being a distal cylindrically shaped segment having a distal end and a proximal end located adjacent the distal end of the intermediate cylindrically shaped segment,

each cylindrically shaped segment being defined by an undulating pattern of interconnected struts, each strut having a proximal end and a distal end, each strut adjacent a first strut and a second strut, the strut and the first strut interconnected only at their distal ends, the strut and the second strut interconnected only at their proximal ends, and

2) a plurality of interconnecting elements including proximal interconnecting elements and distal interconnecting elements, each interconnecting element having a proximal end and a distal end, the proximal end of the interconnecting element circumferentially and longitudinally offset from the distal end of the interconnecting element, the interconnecting elements shorter in length than the cylindrically shaped segments,

each proximal interconnecting element extending proximally from an interconnected proximal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected distal end of adjacent struts on the proximal cylindrically shaped segment,

each distal interconnecting element extending distally from an interconnected distal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected proximal end of adjacent struts on the distal cylindrically shaped segment,

a minimum length pathway of at least three interconnected circumferentially adjacent struts on the intermediate cylindrically shaped segment extending between the distal ends of the proximal interconnecting elements and the proximal ends of the distal interconnecting elements,

wherein upon expansion of the stent interconnected ends of adjacent struts in the proximal cylindrically shaped segment are circumferentially displaced relative to interconnected ends of adjacent struts in the intermediate cylindrically shaped segment and interconnected ends of adjacent struts in the intermediate cylindrically shaped segment are circumferentially displaced relative to interconnected ends of adjacent struts in the distal cylindrically shaped segment to accommodate longitudinal flexing of the stent substantially within the cylindrically shaped segments without substantial flexing of the interconnecting elements and without interference between adjacent cylindrically shaped segments.

9. The stent of claim 8 wherein each interconnecting element extends from a side of an interconnected end of adjacent struts on one cylindrically shaped segment to a side of an interconnected end of adjacent struts on an adjacent cylindrically shaped segment.

10. The stent of claim 8 wherein circumferentially adjacent interconnecting elements are separated by six struts.

11. The stent of claim 8 wherein there are at least three interconnecting elements extending between any two adjacent cylindrically shaped segments.

12. A tubular, flexible, self-expandable stent comprising:

1) a plurality of cylindrically shaped segments which are interconnected,

one of the cylindrically shaped segments being an intermediate cylindrically shaped segment having a proximal end and a distal end,

one of the cylindrically shaped segments being a proximal cylindrically shaped segment having a proximal end and a distal end located adjacent the proximal end of the intermediate cylindrically shaped segment and

one of the cylindrically shaped segments being a distal cylindrically shaped segment having a distal end and a proximal end located adjacent the distal end of the intermediate cylindrically shaped segment,

each cylindrically shaped segment being defined by an undulating pattern of interconnected struts, each strut having a proximal end and a distal end, each strut adjacent a first strut and a second strut, the strut and the first strut interconnected only at their distal ends, the strut and the second strut interconnected only at their proximal ends, and

2) a plurality of interconnecting elements including proximal interconnecting elements and distal interconnecting elements, each interconnecting element having a proximal end and a distal end, the proximal end of the interconnecting element circumferentially and longitudinally offset from the distal end of the interconnecting element, the interconnecting elements shorter in length than the cylindrically shaped segments,

each proximal interconnecting element extending proximally from an interconnected proximal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected distal end of adjacent struts on the proximal cylindrically shaped segment,

each distal interconnecting element extending distally from an interconnected distal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected proximal end of adjacent struts on the distal cylindrically shaped segment,

the interconnecting elements extending at an oblique angle relative to the longitudinal axis, a minimum length pathway of at least three interconnected circumferentially adjacent struts on the intermediate cylindrically shaped segment extending between the distal ends of the proximal interconnecting elements and the proximal ends of the distal interconnecting elements, at least three interconnecting elements extending between any two adjacent cylindrically shaped segments,

wherein upon expansion of the stent interconnected ends of adjacent struts in the proximal cylindrically shaped segment are displaced circumferentially relative to interconnected ends of adjacent struts in the intermediate cylindrically shaped segment and interconnected ends of adjacent struts in the intermediate cylindrically shaped segment are circumferentially displaced relative to interconnected ends of adjacent struts in the distal cylindrically shaped segment to accommodate longitudinal flexing of the stent substantially within the cylindrically shaped segments and without interference between adjacent cylindrically shaped segments.

13. The stent of claim 12 wherein the direction of the interconnecting elements reverses between adjacent pairs of interconnected segments.

14. The stent of claim 12 wherein circumferentially adjacent interconnecting elements are separated by six struts.

15. The stent of claim 1 wherein the direction of the interconnecting elements reverses between adjacent pairs of interconnected cylindrically shaped segments.

16. The stent of claim 8 wherein the direction of the interconnecting elements reverses between adjacent pairs of interconnected cylindrically shaped segments.

17. A tubular, flexible, self-expandable stent comprising:

1) a plurality of cylindrically shaped segments which are interconnected including

a first cylindrically shaped segment defined by an undulating pattern of interconnected first struts, each first strut having a proximal end and a distal end, first struts which are circumferentially adjacent one another and connected at the proximal ends of the first struts forming first troughs, first struts which are circumferentially adjacent one another and connected at the distal ends of the first struts forming first peaks, the first troughs and the first peaks alternating with one another and circumferentially offset from one another about the first cylindrically shaped segment,

a second cylindrically shaped segment defined by an undulating pattern of interconnected second struts, each second strut having a proximal end and a distal end, second struts which are circumferentially adjacent one another and connected at the proximal ends of the second struts forming second troughs, second struts which are circumferentially adjacent one another and connected at the distal ends of the second struts forming second peaks, the second troughs and the second peaks alternating with one another and circumferentially offset from one another about the second cylindrically shaped segment,

a third cylindrically shaped segment defined by an undulating pattern of interconnected third struts, each third strut having a proximal end and a distal end, third struts which are circumferentially adjacent one another and connected at the proximal ends of the third struts forming third troughs, third struts which are circumferentially adjacent one another and connected at the distal ends of the third struts forming third peaks, the third troughs and the third peaks alternating with one another and circumferentially offset from one another about the third cylindrically shaped segment, and

2) a plurality of first connectors connecting the first cylindrically shaped segment and the second cylindrically shaped segment, each first connector having a first end and a second end circumferentially and longitudinally offset from the first end, each first connector extending from one of the first peaks to one of the second troughs, each first connector extending at an oblique angle relative to the longitudinal axis, first connectors which are adjacent one another separated by six first struts, the first connectors shorter in length than the first and second cylindrically shaped segments,

a plurality of second connectors connecting the second cylindrically shaped segment and the third cylindrically shaped segment, each second connector having a first end and a second end circumferentially and longitudinally offset from the first end, each second connector extending from one of the second peaks to one of the third troughs, each second connector extending at an oblique angle relative to the longitudinal axis, second connectors which are adjacent one another separated by six second struts, the second connectors shorter in length than the second and third cylindrically shaped segments,

the second end of each first connector separated from the first end of a second connector which is nearest to it by at least three second struts,

whereby flexing of the stent occurs substantially in the cylindrically shaped segments.

18. The stent of claim 17 formed of a shape memory metal.

19. The stent of claim 18 formed of nitinol.

20. The stent of claim 17, each first peak having a first side, a second side and a middle portion between the first and second sides, each second trough having a first side, a second side and a middle portion between the first and second sides, each second peak having a first side, a second side and a middle portion between the first and second sides, and each third trough having a first side, a second side and a middle portion between the first and second sides,

wherein each first connector extends from the first side of one of the first peaks to the second side of one of the second troughs and each second connector extends from the first side of one of the second peaks to the second side of one of the third troughs.

21. The stent of claim 17, each first connector having a longitudinal axis and each second connector having a longitudinal axis, the longitudinal axis of each first connector intersecting the longitudinal axis of the second connector nearest to the first connector at an angle, the angle bisected by an imaginary line parallel to the longitudinal axis of the stent.

22. The stent of claim 17 wherein there are at least three first connectors and at least three second connectors.

23. The stent of claim 17 constructed and arranged such that upon expansion of the stent, the first peaks are circumferentially displaced relative to the second troughs and the second peaks are circumferentially displaced relative to the third troughs to accommodate longitudinal flexing of the stent within the cylindrically shaped segments and without interference between adjacent cylindrically shaped segments.

24. The stent of claim 17 wherein the direction of the second connectors is reversed relative to the direction of the first connectors.

25. The stent of claim 17 wherein the first cylindrically shaped segment has a first amplitude characterized by the longitudinal distance between the first peaks and the first troughs and the second cylindrically shaped segment has a second amplitude characterized by the longitudinal distance between the second peaks and the second troughs, the first amplitude different from the second amplitude.

26. The stent of claim 17 wherein the first connectors are longer than the second connectors.

27. A stent having a proximal end and a distal end and a longitudinal axis, the stent comprising:

1) a plurality of undulating cylindrical segments including

a first undulating cylindrical segment comprising a plurality of alternating first peaks and first troughs, the first peaks pointing toward the distal end of the stent, the first troughs pointing toward the proximal end of the stent;

a second undulating cylindrical segment comprising a plurality of alternating second peaks and second troughs, the second peaks pointing toward the distal end of the stent, the second troughs pointing toward the proximal end of the stent;

a third undulating cylindrical segment comprising a plurality of alternating third peaks and third troughs, the third peaks pointing toward the distal end of the stent, the third troughs pointing toward the proximal end of the stent;

2) a plurality of connectors including

a plurality of first connectors connecting the first undulating cylindrical segment and the second undulating cylindrical segment, each first connector having a proximal end and a distal end circumferentially and longitudinally displaced from the proximal end, the proximal end extending from one of the first peaks, the distal end extending from one of the second troughs, the first connectors extending from every third first peak and every third second trough, the first connectors shorter in length than the first undulating cylindrical segment and the second undulating cylindrical segment,

a plurality of second connectors connecting the second undulating cylindrical segment and the third undulating cylindrical segment, each second connector having a proximal end and a distal end circumferentially and longitudinally displaced from the proximal end, the proximal end extending from one of the second peaks, the distal end extending from one of the third troughs, the second connectors extending from every third second peak and every third third trough, the second connectors shorter in length than the second undulating cylindrical segment and the third undulating cylindrical segment, each first connector separated from a second connector which is nearest to it by at least one second peak and one second trough,

wherein flexing of the stent occurs substantially in the undulating cylindrical segments.

28. The stent of claim 27 formed of a shape memory metal.

29. The stent of claim 28 formed of nitinol.

30. The stent of claim 27 wherein there are at least three first connectors connecting the first and second undulating cylindrical segments.

31. The stent of claim 27 constructed and arranged such that upon expansion of the stent, peaks of undulating cylindrical segments are circumferentially displaced relative to troughs of adjacent undulating cylindrical segments to accommodate longitudinal flexing of the stent within the cylindrically shaped segments and without interference between adjacent cylindrically shaped segments.

32. The stent of claim 31 wherein the connectors are substantially linear.

33. The stent of claim 32 wherein the connectors extend diagonally relative to the longitudinal axis of the stent.

34. The stent of claim 27 each first peak having a first side, a second side and a middle portion between the first and second sides, each second trough having a first side, a second side and a middle portion between the first and second sides, each second peak having a first side, a second side and a middle portion between the first and second sides, and each third trough having a first side, a second side and a middle portion between the first and second sides,

wherein each first connector extends from the first side of one of the first peaks to the second side of one of the second troughs and each second connector extends from the first side of one of the second peaks to the second side of one of the third troughs.

35. The stent of claim 27, each first connector having a longitudinal axis and each second connector having a longitudinal axis, the longitudinal axis of each first connector intersecting the longitudinal axis of the second connector nearest to the first connector at an angle, the angle bisected by an imaginary line parallel to the longitudinal axis of the stent.

36. The stent of claim 27 wherein the direction of the second connectors is reversed relative to the direction of the first connectors.

37. The stent of claim 27 wherein the first undulating cylindrical segment has a first amplitude characterized by the longitudinal distance between the first peaks and the first troughs and the second undulating cylindrical segment has a second amplitude characterized by the longitudinal distance between the second peaks and the second troughs, the first amplitude different from the second amplitude.

38. The stent of claim 27 wherein the first connectors are characterized by a first length and the second connectors are characterized by a second length, the first length different from the second length.

39. A stent having a proximal end and a distal end, the stent comprising:

1) a plurality of undulating cylindrical segments including

a first undulating cylindrical segment comprising a plurality of alternating first peaks and first troughs, the first peaks pointing toward the distal end of the stent, the first troughs pointing toward the proximal end of the stent;

a second undulating cylindrical segment comprising a plurality of alternating second peaks and second troughs, the second peaks pointing toward the distal end of the stent, the second troughs pointing toward the proximal end of the stent;

a third undulating cylindrical segment comprising a plurality of alternating third peaks and third troughs, the third peaks pointing toward the distal end of the stent, the third troughs pointing toward the proximal end of the stent; and

2) a plurality of connectors including

a plurality of first connectors connecting the first undulating cylindrical segment and the second undulating cylindrical segment, each first connector having a proximal end and a distal end circumferentially and longitudinally displaced from the proximal end, the proximal end extending from one of the first peaks, the distal end extending from one of the second troughs, the first connectors extending from every third first peak and every third second trough, the first connectors shorter in length than the first undulating cylindrical segment and the second undulating cylindrical segment,

a plurality of second connectors connecting the second undulating cylindrical segment and the third undulating cylindrical segment, each second connector having a proximal end and a distal end circumferentially and longitudinally displaced from the proximal end, the proximal end extending from one of the second peaks, the distal end extending from one of the third troughs, the second connectors extending

from every third second peak and every third third trough, the second connectors shorter in length than the second undulating cylindrical segment and the third undulating cylindrical segment,

each first connector separated from a second connector which is nearest to it by at least one second peak and one second trough,

wherein upon expansion of the stent the first peaks are circumferentially displaced relative to the second troughs and the second peaks are circumferentially displaced relative to the third troughs to accommodate longitudinal flexing of the stent substantially within the undulating cylindrical segments without substantial flexing of the connectors, without interference between the first and second undulating cylindrical segments and without interference between the second and third undulating cylindrical segments.

40. The stent of claim 1 wherein in interconnecting elements are of a shorter length than the struts.

41. The stent of claim 17 wherein the first connectors are shorter than the second connectors.

42. A stent comprising:

1) a plurality of cylindrically shaped segments which are interconnected,

one of the cylindrically shaped segments being an intermediate cylindrically shaped segment having a proximal end and a distal end,

one of the cylindrically shaped segments being a proximal cylindrically shaped segment having a proximal end and a distal end located adjacent the proximal end of the intermediate cylindrically shaped segment and

one of the cylindrically shaped segments being a distal cylindrically shaped segment having a distal end and a proximal end located adjacent the distal end of the intermediate cylindrically shaped segment,

each cylindrically shaped segment being defined by an undulating pattern of interconnected struts, each strut having a proximal end and a distal end, each strut adjacent a first strut and a second strut, the strut and the first strut interconnected only at their distal ends, the strut and the second strut interconnected only at their proximal ends, and

2) a plurality of interconnecting elements including proximal interconnecting elements and distal interconnecting elements, each interconnecting element having a proximal end and a distal end, the proximal end of the interconnecting element circumferentially and longitudinally offset from the distal end of the interconnecting element, the interconnecting elements shorter in length than the cylindrically shaped segments,

each proximal interconnecting element extending proximally from an interconnected proximal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected distal end of adjacent struts on the proximal cylindrically shaped segment,

each distal interconnecting element extending distally from an interconnected distal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected proximal end of adjacent struts on the distal cylindrically shaped segment,

the interconnecting elements non-parallel to the longitudinal axis, a minimum length pathway of at least three interconnected circumferentially adjacent struts on the intermediate cylindrically shaped segment extending between the distal ends of the proximal interconnecting elements and the proximal ends of the distal interconnecting elements,

wherein flexing of the stent occurs substantially in the cylindrically shaped segments.

43. The stent of claim 42 wherein circumferentially adjacent interconnecting elements are separated by six struts.

44. A stent comprising:

1) a plurality of cylindrically shaped segments which are interconnected,

one of the cylindrically shaped segments being an intermediate cylindrically shaped segment having a proximal end and a distal end,

one of the cylindrically shaped segments being a proximal cylindrically shaped segment having a proximal end and a distal end located adjacent the proximal end of the intermediate cylindrically shaped segment and

one of the cylindrically shaped segments being a distal cylindrically shaped segment having a distal end and a proximal end located adjacent the distal end of the intermediate cylindrically shaped segment,

each cylindrically shaped segment being defined by an undulating pattern of interconnected struts, each strut having a proximal end and a distal end, each strut adjacent a first strut and a second strut, the strut and the first strut interconnected only at their distal ends, the strut and the second strut interconnected only at their proximal ends, and

2) a plurality of interconnecting elements including proximal interconnecting elements and distal interconnecting elements, each interconnecting element having a proximal end and a distal end, the proximal end of the interconnecting element circumferentially and longitudinally offset from the distal end of the interconnecting element, the interconnecting elements shorter in length than the cylindrically shaped segments,

each proximal interconnecting element extending proximally from an interconnected proximal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected distal end of adjacent struts on the proximal cylindrically shaped segment,

each distal interconnecting element extending distally from an interconnected distal end of adjacent struts on the intermediate cylindrically shaped segment to an interconnected proximal end of adjacent struts on the distal cylindrically shaped segment,

the interconnecting elements non-parallel to the longitudinal axis, a minimum length pathway of at least three interconnected circumferentially adjacent struts on the intermediate cylindrically shaped segment extending between the distal ends of the proximal interconnecting elements and the proximal ends of the distal interconnecting elements, at least three interconnecting elements extending between any two adjacent cylindrically shaped segments,

wherein upon expansion of the stent interconnected ends of adjacent struts in the proximal cylindrically shaped segment are displaced circumferentially relative to interconnected ends of adjacent struts in the intermediate cylindrically shaped segment and interconnected ends of adjacent struts in the intermediate cylindrically shaped segment are circumferentially displaced relative to interconnected ends of adjacent struts in the distal cylindrically shaped segment to accommodate longitudinal flexing of the stent substantially within the cylindrically shaped segments and without interference between adjacent cylindrically shaped segments.

45. The stent of claim 44 wherein circumferentially adjacent interconnecting elements are separated by six struts.

* * * * *

EXHIBIT N

US005776161A

United States Patent [19]

Globerman

[11] Patent Number: 5,776,161

[45] Date of Patent: Jul. 7, 1998

[54] **MEDICAL STENTS, APPARATUS AND METHOD FOR MAKING SAME**

[75] Inventor: **Oren Globerman**, Holon, Israel

[73] Assignee: **Instent, Inc.**, Eden Prairie, Minn.

[21] Appl. No.: **543,337**

[22] Filed: **Oct. 16, 1995**

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **606/194**; 606/192; 623/1

[58] **Field of Search** 606/192, 194, 606/198, 191; 623/1, 12

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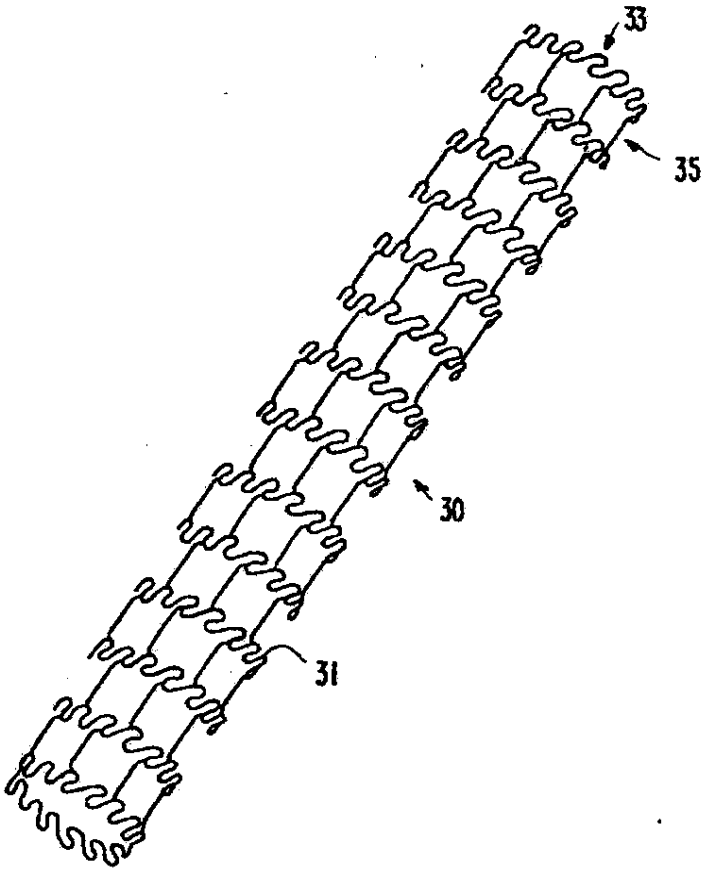
Primary Examiner—Michael Buiz
Assistant Examiner—Patrick W. Rasche
Attorney, Agent, or Firm—Levisohn, Lerner, Berger & Langsam

[57] **ABSTRACT**

An expandable stent and stent graft having a small initial diameter, flexibility along its longitudinal axis prior to expansion and a large expanded and rigid Local strain on the stent material is minimized, as and after the balloon is expanded. More particularly, the stent has rotation joints having minimal strain during stent expansion. The stent is substantially the same length before and after expansion and being flexible longitudinally when constrained, it is easy to locate. A method of manufacturing stents is described comprising rotation of a tube beneath a moving film, with light passing through the film onto the tube, at selected locations. A laser scanning system for stent manufacture is also disclosed.

25 Claims, 12 Drawing Sheets



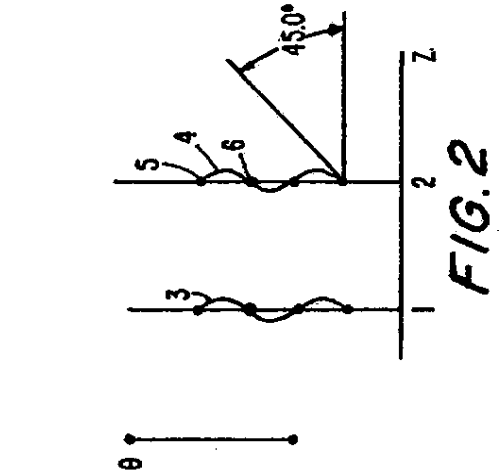
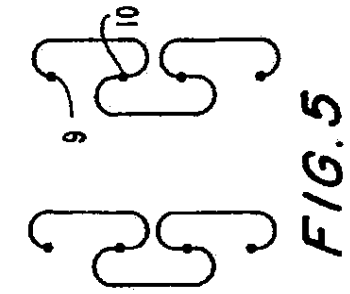


FIG. 2



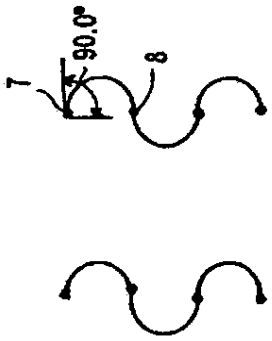


FIG. 5

FIG. 4

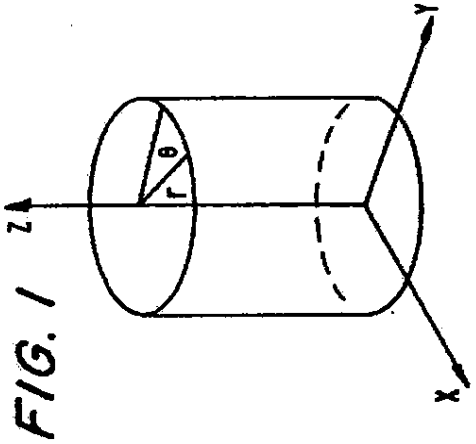


FIG. 1

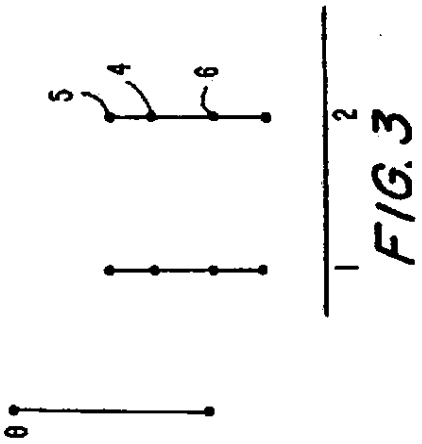


FIG. 3

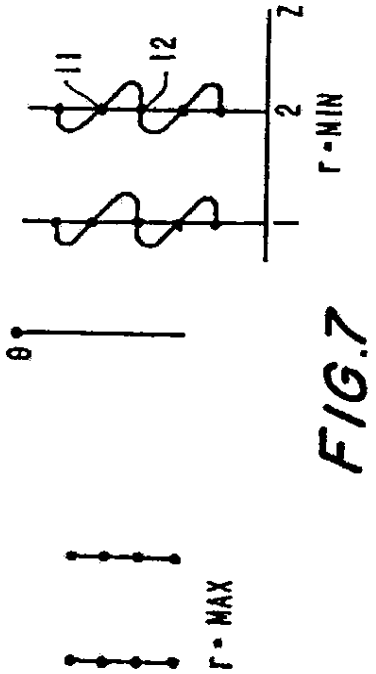


FIG.7

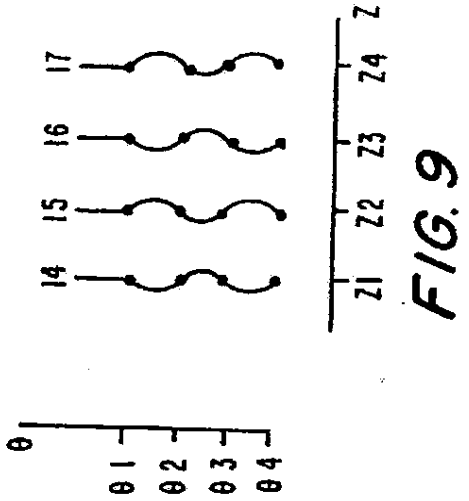


FIG.9

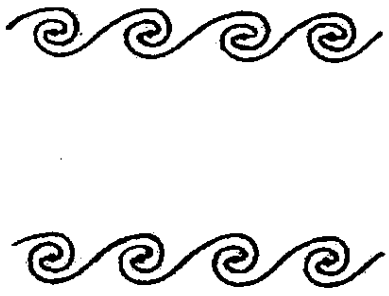


FIG.6

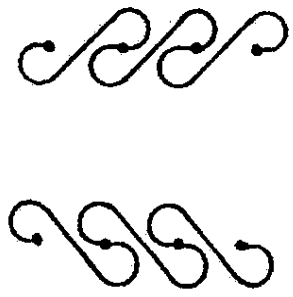
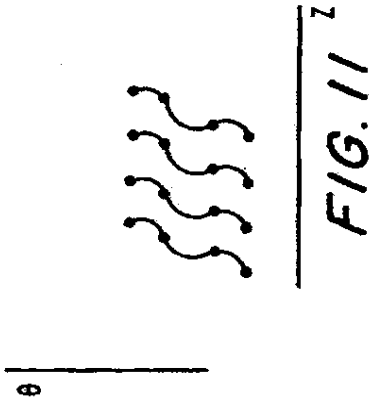


FIG.8



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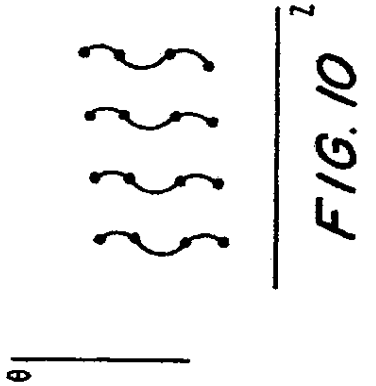

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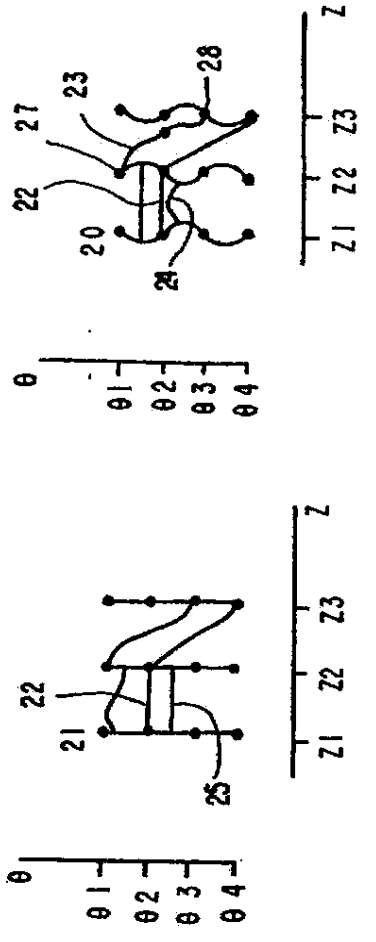

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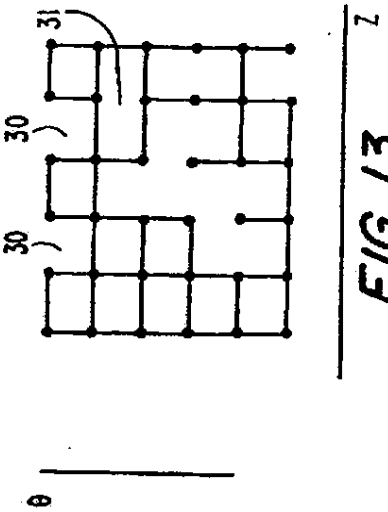


FIG. 13

FIG. 14

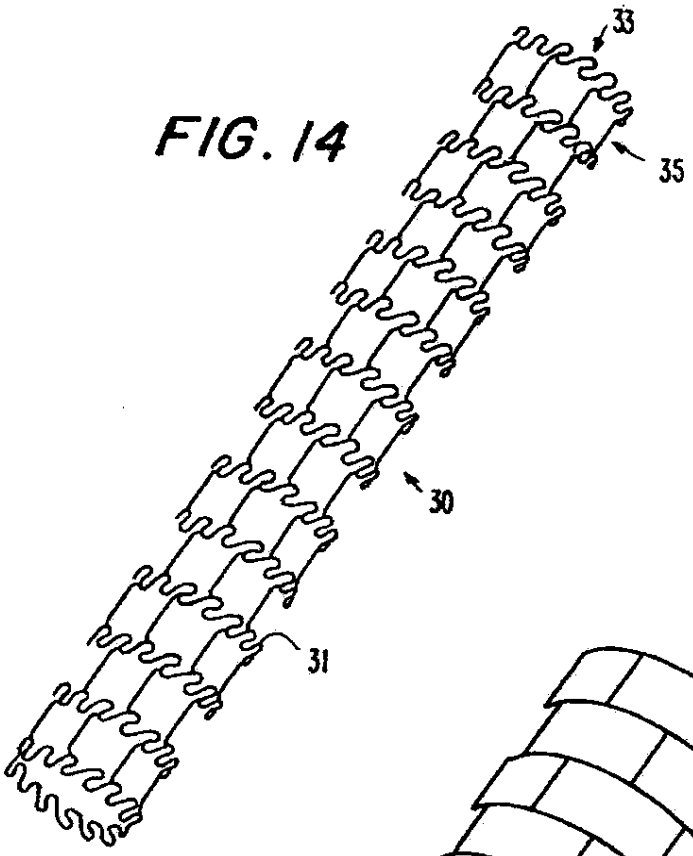


FIG. 15

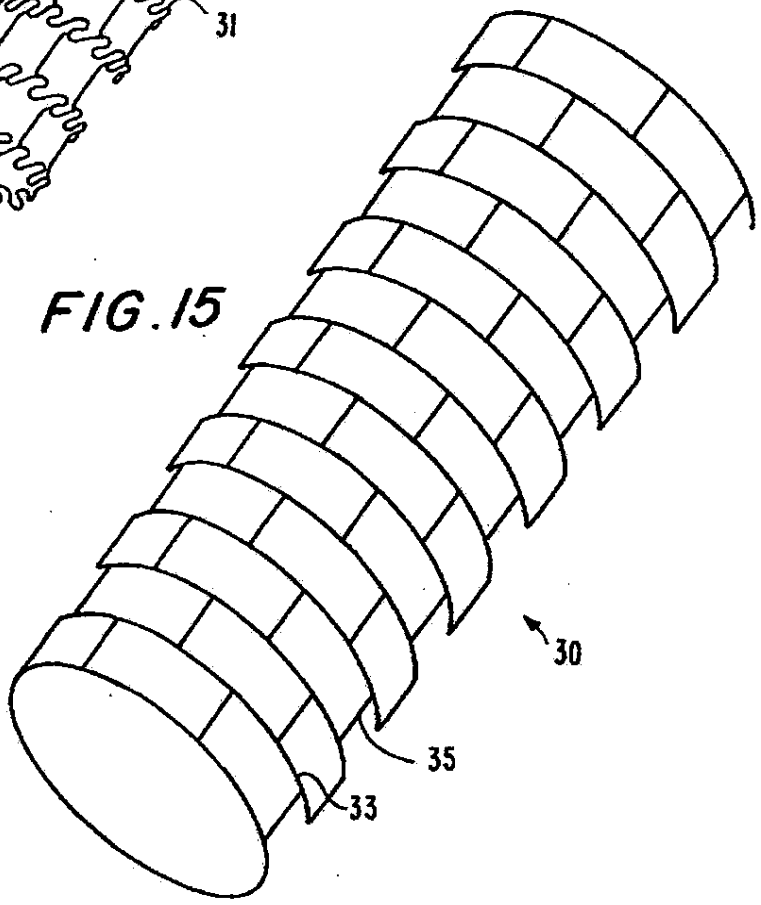


FIG. 16

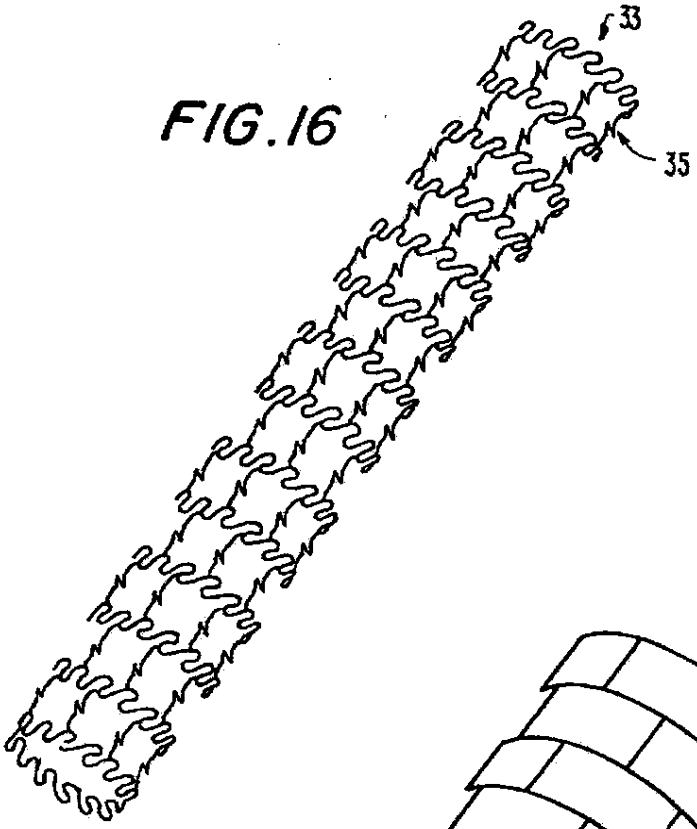


FIG. 17

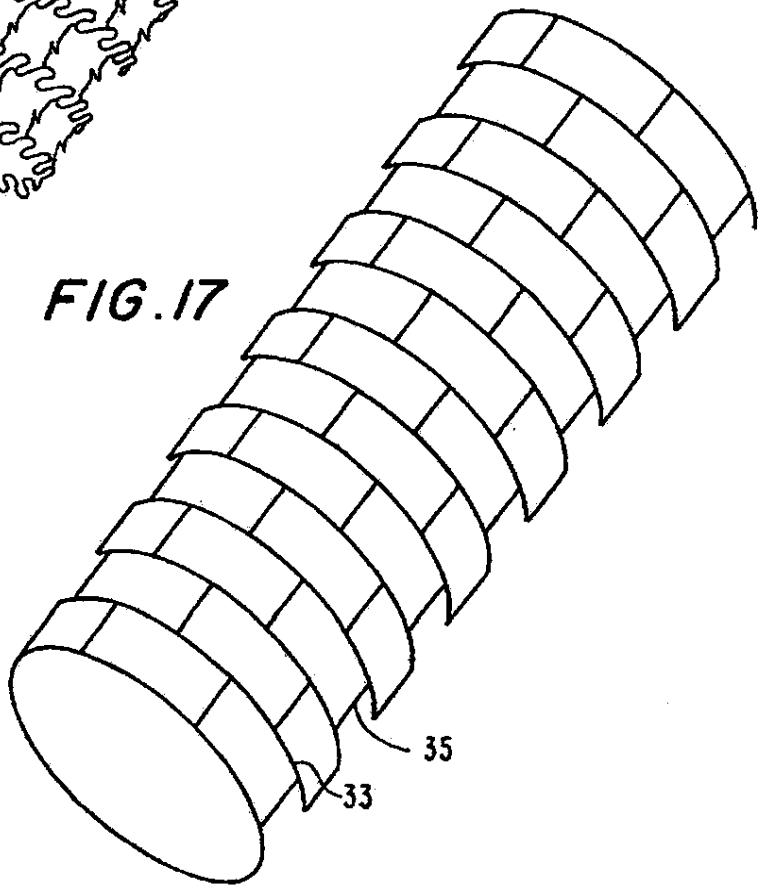


FIG. 18

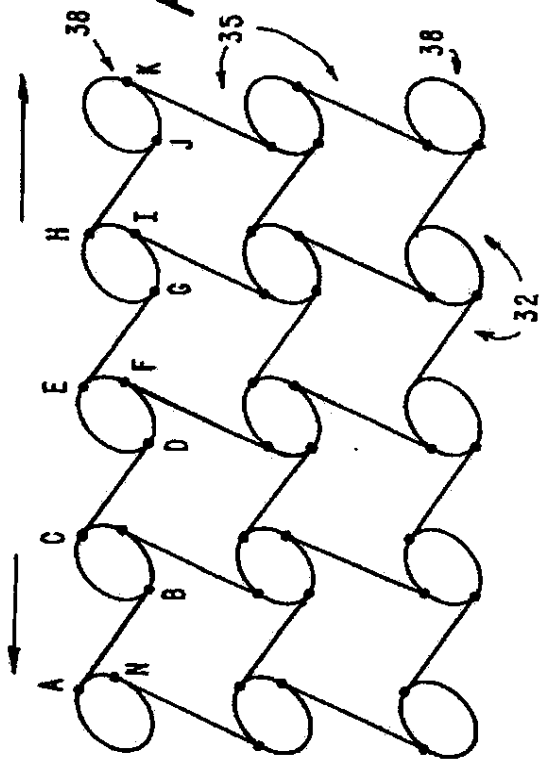
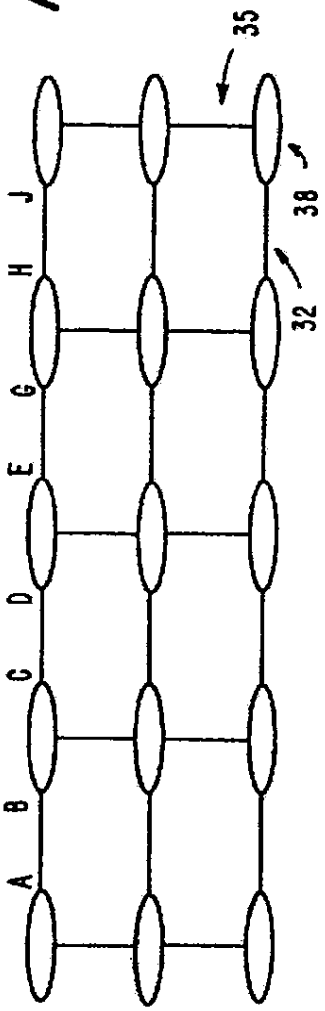


FIG. 19



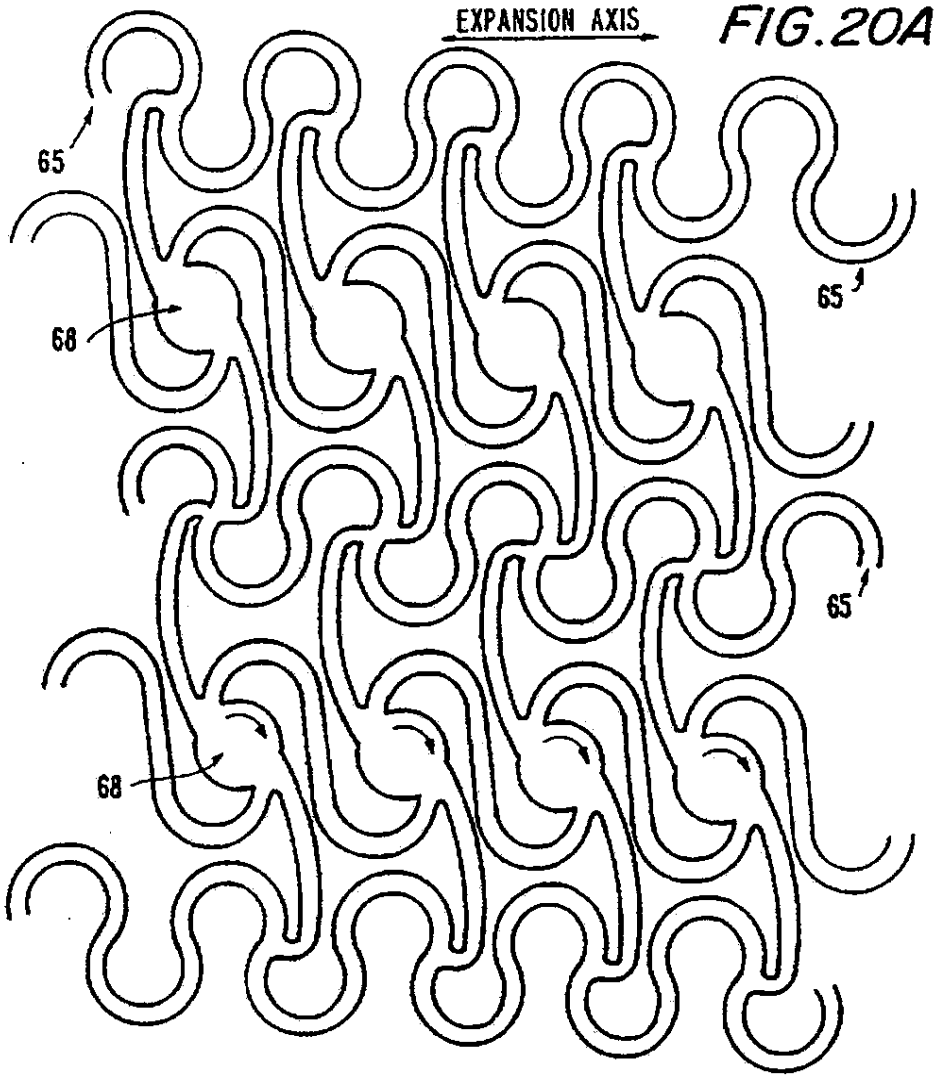


FIG. 20A

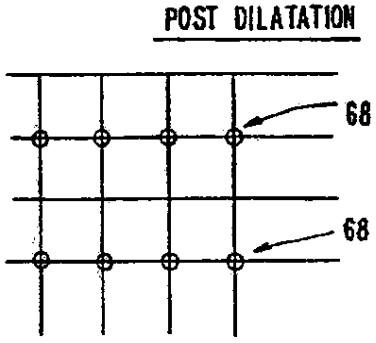


FIG. 20B

FIG. 21

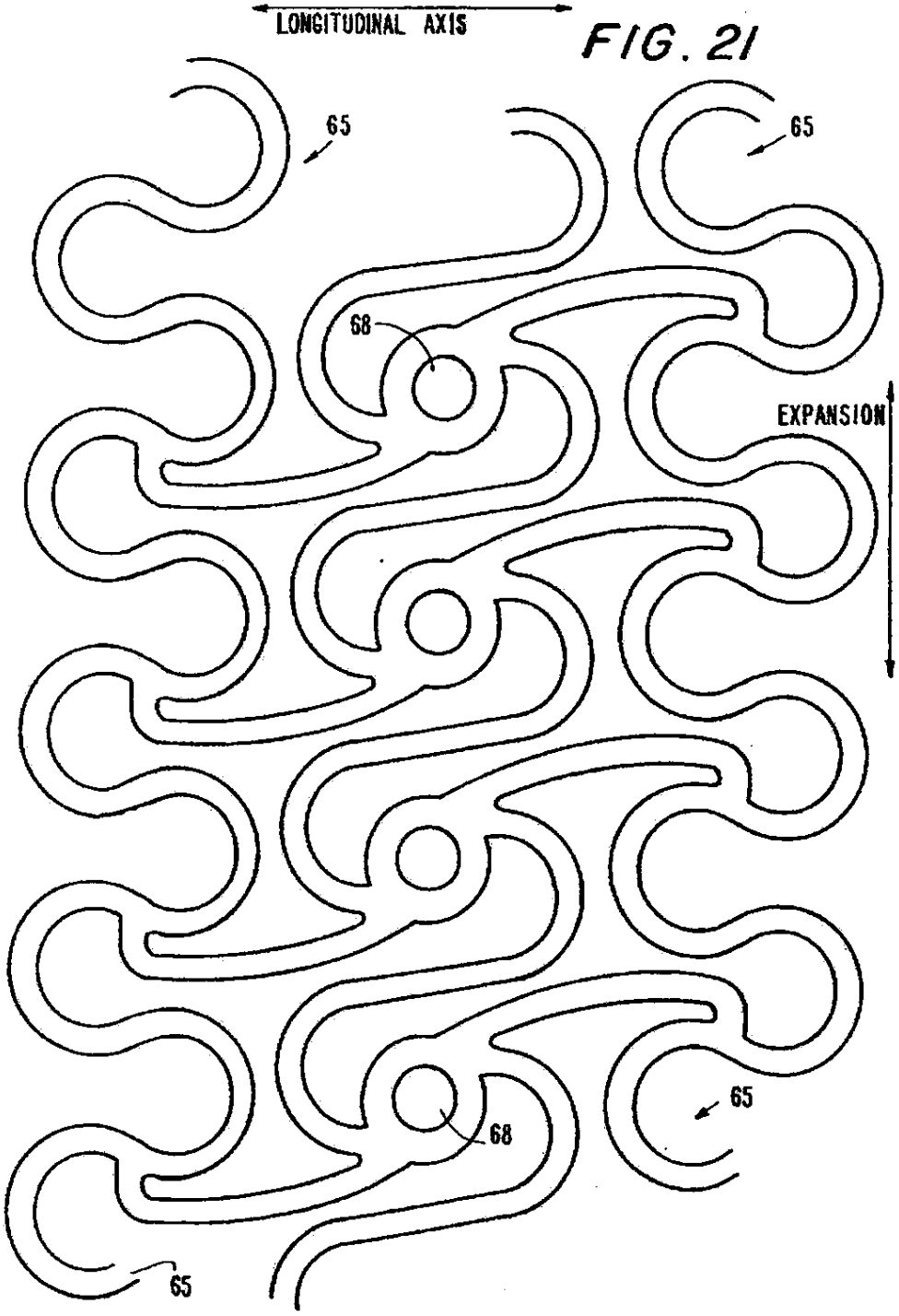


FIG. 22

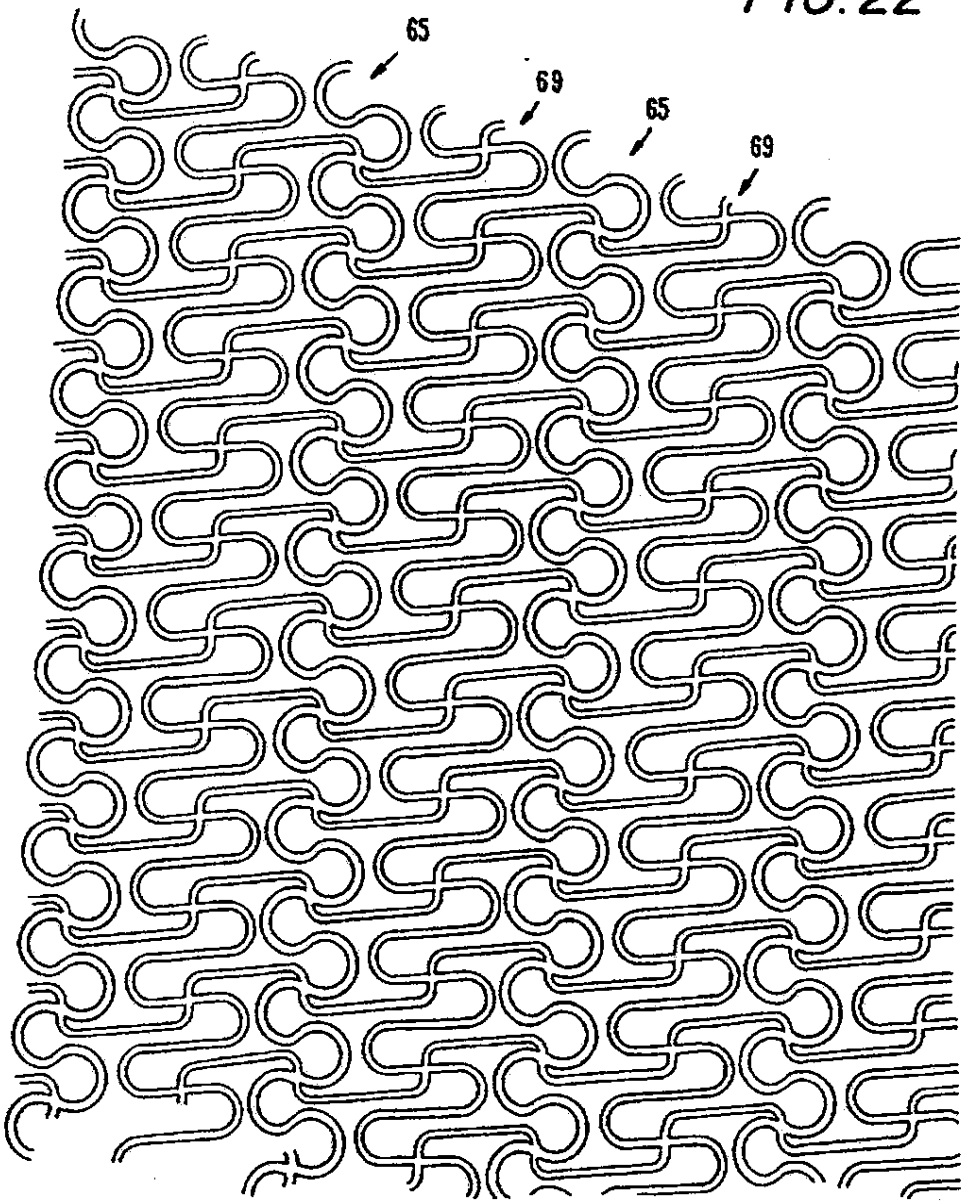


FIG. 23

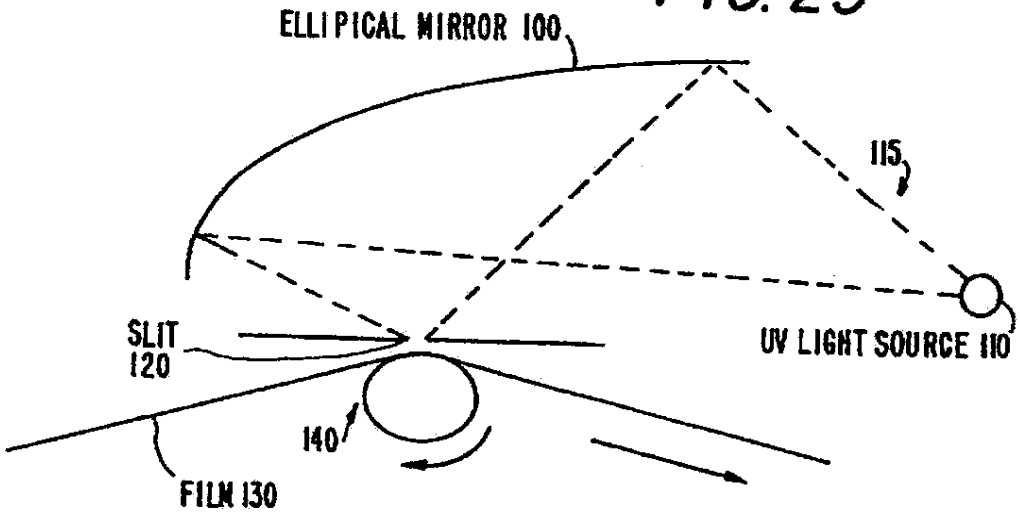

ELLIPICAL MIRROR 100
115
SLIT
120
UV LIGHT SOURCE 110
140
FILM 130

FIG. 24

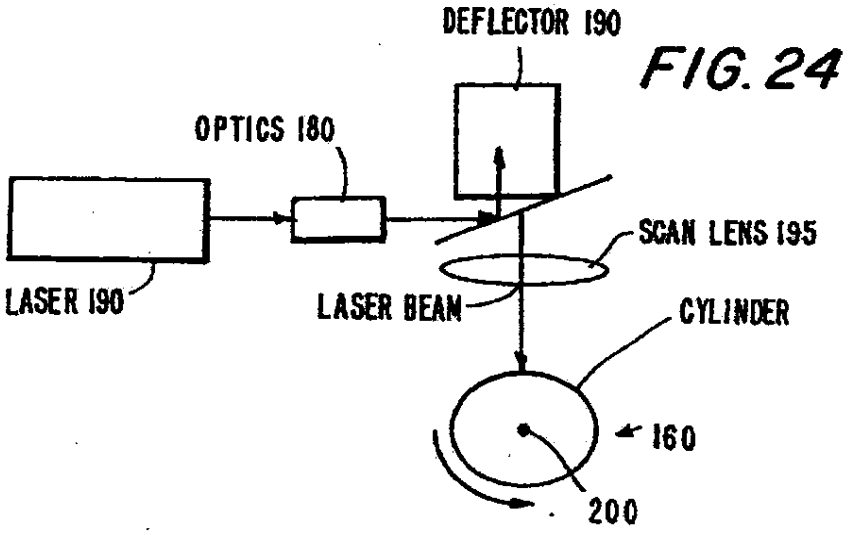

DEFLECTOR 190
OPTICS 180
SCAN LENS 195
LASER 190
LASER BEAM
CYLINDER
160
200

FIG. 25

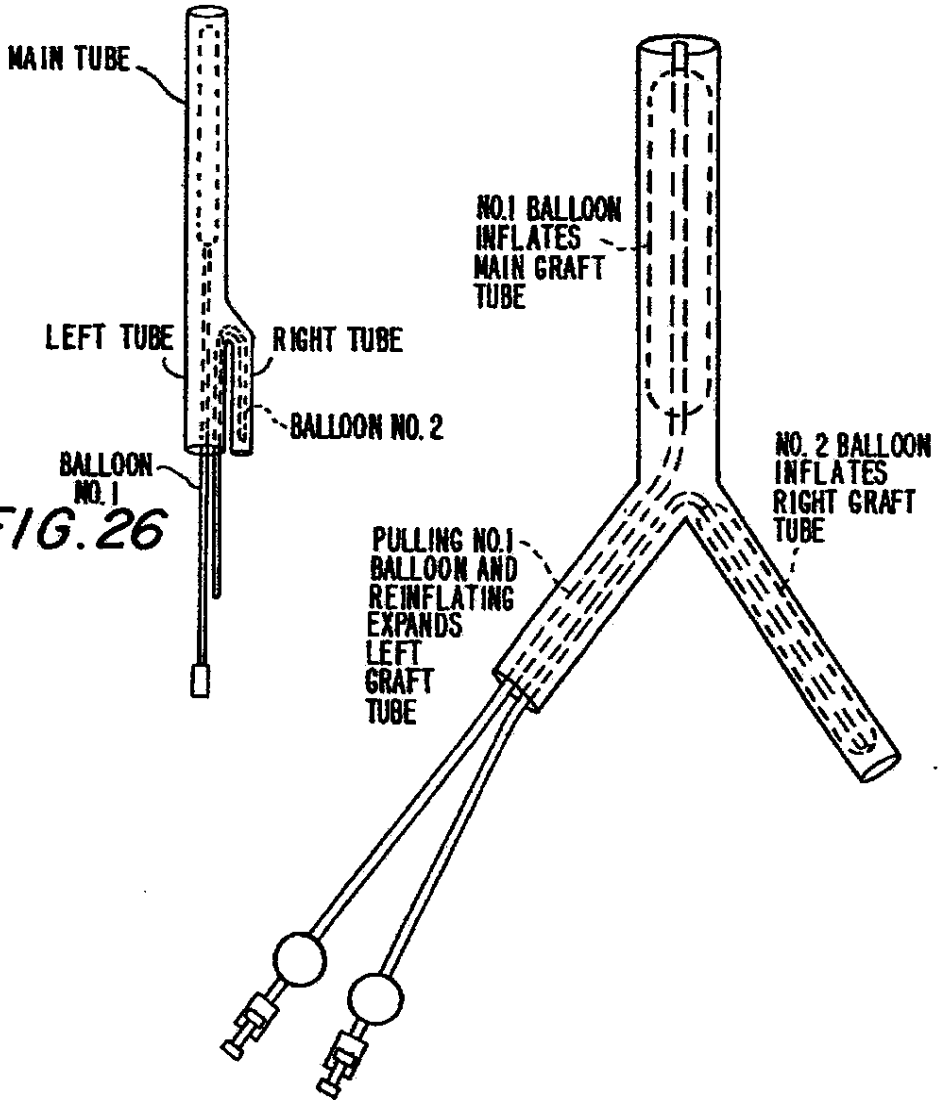

MAIN TUBE
NO.1 BALLOON INFLATES MAIN GRAFT TUBE
LEFT TUBE
RIGHT TUBE
BALLOON NO. 2
BALLOON NO. 1
NO. 2 BALLOON INFLATES RIGHT GRAFT TUBE
PULLING NO.1 BALLOON AND REINFLATING EXPANDS LEFT GRAFT TUBE

FIG. 26

FIG. 27

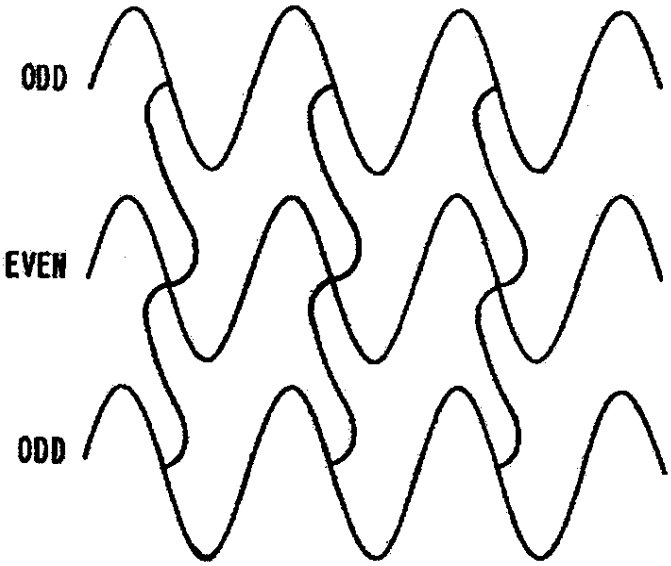
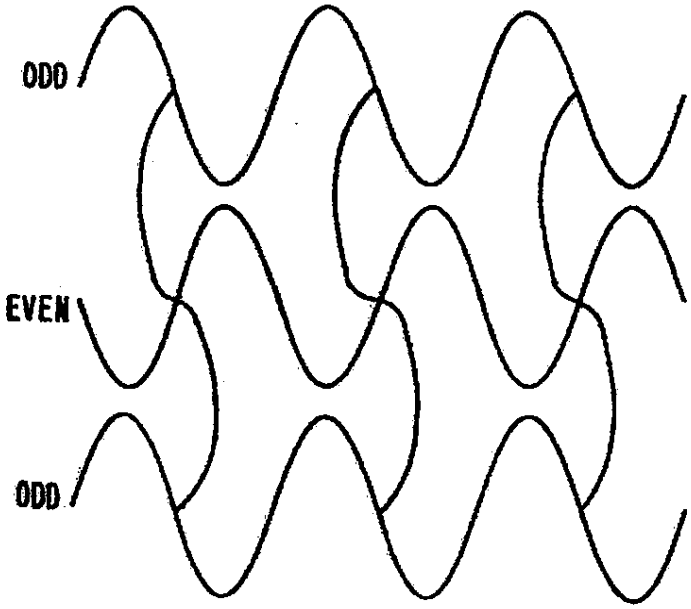


FIG. 28



MEDICAL STENTS, APPARATUS AND METHOD FOR MAKING SAME

FIELD OF THE INVENTION

The present invention relates to an improved stent and stent graft for use in constricted body tubes, and for widening a stenosis in a body cavity such as in an artery, in the bile duct, esophagus, and so forth. The present invention also relates to stent production technology, and a method for manufacture of the improved stent device.

BACKGROUND OF THE INVENTION AND DESCRIPTION OF THE PRIOR ART

Intraluminal endovascular stenting is a method by which a prosthesis is inserted into a body tube and expanded so as to reopen a collapsed vessel wall and prevent the wall from recollapsing into the lumen. Endovascular stenting is particularly useful for arteries which are blocked or narrowed and is an alternative to surgical procedures that intend to bypass the occlusion.

Previous structures used as stents or intraluminal vascular grafts have included coiled stainless steel springs; helical wound spring coil made from shape memory alloy; expanding metal stents formed in a zig-zag pattern; diamond shaped, rectangular shaped, and other mesh and non-mesh designs. Some of the stents currently available employ a self expanding concept, whereby stent expansion is primarily achieved by removing a restraint mechanism holding the stent in a constricted configuration. Other stents in the prior art are delivered to the site by a balloon catheter system, and primarily employ balloon dilation to achieve proper stent expansion.

Problems with this variety of stents is inadequate radial force to maintain expansion; inappropriate scaffolding of tissue to the wall; pre-dilated longitudinal rigidity which negatively impacts on stent delivery; and shortening of the stent as a consequence of radial expansion. Predilation stent longitudinal rigidity is a significant shortcoming, and prevents the threading of the stent through long tortuous vessels and lesions. Shortening of the stent is also a problem, as it is important that the stent cover the entire lesion to minimize the risk of post-operative complications. Obviously, therefore, there is a need for a long yet flexible stent that will provide the appropriate scaffolding effect, will be able to track well in-curved vessels, will not shorten during radial expansion, and yet will have sufficient outward radial force to hold the artery open, even in the presence of hard calcified lesions. The stent disclosed herein overcomes these disadvantages. No stent having all of the desired features appears to exist, prior to this invention which achieves most of these properties.

As is well known, a traditional alternative to conventional vascular surgery has been percutaneous transluminal balloon angioplasty (PCTA). In this procedure, the angioplasty balloon is inflated within the stenosed artery to create, through shearing and mechanical trauma, a larger inner lumen. This process, while successful in achieving a larger lumen in most cases, can sometimes cause local tears, dissections and protrusion of plate into the lumen so that vessel blockage is caused rather than the desired vessel opening. In addition, the phenomenon of elastic recoil and intimal growth following arterial dilation often causes late restenosis (within six months) in more than about 30% of the patients undergoing the angioplasty balloon procedure. Because of the fear of the acute complication of sudden occlusion (abrupt closure), a surgical backup is needed in

most places where PTCA is performed. This is yet another limitation of the mechanical balloon dilatation procedure.

It has been shown that stenting results in excellent acute results with adequate scaffolding of tears to the wall of the artery and with generation of a large inner lumen. This large inner lumen, initially present after stenting, has a lower restenosis rate after the procedure, as shown in the STRESS (N. Engl. J. Med. 1994; 331:L 496–501) and BENESTENT (N. Engl. J. Med. 1994; 331: 489–95) studies. While the inner lumen achieved using the self-expanding stents depends on the sizing of the stents relative to the vessel, the inner lumens that can be achieved with balloon expandable stents depend both on the size and radially expanding pressure of the balloon. The inner lumens achievable with balloon expandable stents can be further increased with further inflation of the balloon.

One of the major complications associated with stent use has been thrombosis. The problem occurs most commonly between day 2 and 6 of the implantation, but may also occur as late as 3 weeks after stenting. This complication is caused by clotting of the stent and is associated with high morbidity and mortality. It has been recently shown that the better the stent apposition against the wall and the larger the lumen is, the less likely that this complication will occur. In addition, it is very important that the stent cover the entire lesion since the existence of obstructions before or after the stent may also cause a complication.

The current balloon expandable stents have the significant limitation of relative, longitudinal rigidity during delivery, and so do not allow for a very long stent to traverse the usual curves in the artery. This longitudinal rigidity during delivery is sought to be avoided by devices taught in the patents to Wolff (U.S. Pat. No. 5,104,404) and to Pinchasik (U.S. Pat. No. 5,449,373) in which the rigid Palmaz stent sections are connected together with flexible connections. For this reason, it is required that the stent be long (to allow treatment of long lesions) and flexible upon insertion to site (to allow passage to and through tortuous locations) but yet have large radial force to unblock the vessel and excellent scaffolding so as to be able to hold the atherosclerotic material against the wall, even in bends and in hard calcified lesions. The stent should also allow for further balloon expansion if further lumen enlargement is required at particular locations.

In U.S. Pat. No. 5,104,404, Pinchasik attempts to address some of the shortcomings of the prior art by teaching the use of different connectors (articulation) between the rigid Palmaz stent segments, enabling more flexibility between the rigid parts.

It would be highly desirable, however, to have a stent having few or no longitudinally rigid parts so that it will be homogeneously flexible along its entire longitudinal axis when delivered on the catheter. Furthermore it would be extremely desirable to eliminate the longitudinal shortening of the stent during radial expansion to minimize stent misplacement.

Furthermore, in Palmas' stents marketed by Johnson & Johnson, as well as in others, during plastic deformation of the stent (i.e. balloon expansion) the strain is concentrated at small zones. This limits the properties of the material that can be used as well as the radial force and the expansion rate. By distributing the strain over large zones, a less thick annealed material can be used to both avoid deterioration of the radial force of the stent when expanded, and to reduce the stent's constricted profile. There are obvious advantages to reduced stent thickness.

According to the prior art method of manufacturing stents, the material is originally flat. The screen-like material is then rolled into a cylinder shape and laser welded or otherwise connected to form a tube—the weld running the length of the longitudinal axis. This is a difficult and expensive manufacturing procedure. It also leads to a potential lack of uniformity. The present invention, a new method of stent manufacture, as will be explained, results in a more uniformly expandable stent, one not having a weld line formed after mesh formation.

Patents which relate to the field of stent geometry are as follows: U.S. Pat. Nos. 5,354,309; 4,776,337; 5,356,423; 5,383,892; 5,178,618; 5,449,373; and 5,104,404.

SUMMARY OF THE INVENTION

The object of the present invention is to provide a stent which has flexibility substantially along its longitudinal axis when constrained on a catheter to allow it to easily pass through and along highly curved body vessels and fluid-carrying tubes.

It is further an object of the invention to supply the constricted stent (i.e., before balloon expansion) with a minimum diameter to ease its passage for placement through a minimal diameter vascular port as well as to enable it to enter through narrow lumens of constricted body tubes.

It is further an object of the invention to provide a stent geometry which results in a more homogenous distribution of the strain on the stent material, reducing the maximum strain on the stent when expanded so that less material can be used. Subjecting less material to the same balloon-expanding force can result in greater radial expansion. This allows both a greater expansion ratio for the stent and smaller stent wall thickness.

It is further an object of this invention to allow a stent geometry and proper material to provide additional stent diameter expansion by elongation of the stent material (such as tantalum) and not by changing the shape of the stent.

It is further an object of the invention to provide a stent which does not substantially change in length as the stent diameter is expanded during balloon inflation.

A further object of the present invention is to provide a method for fabricating stents and, in particular, the stents disclosed herein.

It is a further object of the invention to supply the stent with a graft material to be a stent graph as well as a stent graft of Y-shape for aortic aneurism.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view of a stent (shown as a cylinder for illustrative purposes) in cylindrical coordinates;

FIG. 2 is a partial section of a stent, showing a pair of radial rings, unconnected in the longitudinal direction (for illustration) and showing a stent before expansion, having points or dots on the rings which will rotate 45° upon expansion due to balloon inflation. (In FIGS. 21–11, the interconnections between the adjacent radial rings of the stent are not shown.). A ring of the stent resembles a lock washer, an undulating ring shape;

FIG. 3 is a partial section of a stent showing the pair of adjacent radial rings of FIG. 2, after expansion of the stent;

FIG. 4 is a partial section of a pair of radial rings of a second embodiment of a stent, without longitudinal connection (for ease of illustration) before expansion, having points or dots on the rings which will rotate 90° upon stent expansion;

FIG. 5 is a partial section of another embodiment of a stent showing a pair of radial rings, before expansion, having points or dots on the rings which will rotate 180° upon expansion;

FIG. 6 is a partial section of a pair of radial rings of another embodiment of the stent, again, before expansion, having points or dots on the rings which will rotate 360° upon expansion;

FIG. 7 is a partial section of a pair of radial rings of another embodiment of the stent, both before (on the right side) and after (on the left side) expansion, having two types of dots or points on the rings which will rotate through angles of 45° and 90° respectively, upon expansion;

FIG. 8 shows a partial section of a pair of radial rings of another embodiment of the stent, before expansion, in which the radial rings have two types of dots or points on the rings which will rotate through angles of 45° and 180°, respectively, upon expansion;

FIG. 9 shows two pairs of radial rings of yet another embodiment of the stent, before expansion, in which adjacent rings are constructed with mirror images of each other;

FIG. 10 shows four radial rings in which neighboring rings are offset, i.e., have constructions which differ by an angle of rotation from each other. The "z" and "θ" angles are shown on the axis; the "θ" axis, corresponds to the angle "θ" illustrated in FIG. 1;

FIG. 11 shows a partial section of four rings of yet another embodiment of a stent, before expansion;

FIG. 12 shows a graphical depiction of two types of longitudinal connections between neighboring radial rings of a stent, the right side of the Figure being before stent expansion;.

FIG. 13 shows a graphical representation of a section of an expanded stent which has been constructed such that some of the radial segments and some of the longitudinal connections are deliberately omitted during manufacture;

FIG. 14 is a perspective view of a stent according to the present invention with the stent in its constricted form, prior to expansion and wherein the connections between adjacent rings of the stent are straight;

FIG. 15 is a perspective view of the stent of FIG. 14 with the stent in its expanded form;

FIG. 16 is a perspective view of another embodiment of a stent in which the connections between the adjacent rings of the stent are also curved. The stent is shown in the constricted form prior to expansion;

FIG. 17 is a perspective view of the stent of FIG. 16 in its expanded form;

FIG. 18 shows an enlarged partial section of another embodiment of a stent in which the stent joints (between the adjacent rings) are circular, and the stent is in its constricted form, prior to the expansion. Individual rings are formed with the circular joints, as well;

FIG. 19 shows the portions of the stent of FIG. 18 in its expanded form. Points A, B, C, D, E, F, G, H, I, J and K have been shown on both FIGS. 18 and 19 (opposed, offset U-shapes) to illustrate relative movement and location, a consequence of stent expansion;

FIG. 20A shows a partial enlarged section of another embodiment of a stent with undulated (opposed, offset U-shapes) rings, strips or segments separating adjacent rings, and alternate rings having simple intersections between adjacent points on the same ring and circular joints between adjacent points. FIG. 20A shows the stent in a

constricted form; FIG. 20B is a schematic representation of the stent of FIG. 20A in an expanded form;

FIGS. 21 and 22 show partial sections of a stent with undulated (opposed, offset U-shapes) radial strips or segments as in FIG. 20A, forming the rings, yet with the circular connectors being hollow. The rings are connected by longitudinal segments;

FIG. 22 shows another embodiment with undulating rings, longitudinal connectors and simple intersections;

FIG. 23 is a side elevational schematic view of a film contact imaging apparatus for stent manufacture;

FIG. 24 is a similar schematic view of a laser scanning system for stent manufacture;

FIG. 25 is a schematic representation of a Y-tube stent graft in the open position, according to the present invention;

FIG. 26 is a schematic representation of a Y-tube stent graft in the closed configuration.

FIG. 27 is an enlarged partial view of the stent of the present invention, in an embodiment where all the rings are in phase; and

FIG. 28 is an enlarged partial view of the stent of the present invention, in an embodiment where adjacent or paired rings are 180 degrees out of phase with one another. Of course, as will be appreciated from the description of the drawings and of the invention, all angles between 0 degrees and 180 degrees can be used for the lateral offset of the "peaks" and "valleys" of the adjacent rows. FIG. 28 shows that the repetitive "peaks" and "valleys" of adjacent rings are offset by about 150 to 160 degrees.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a novel stent construction. The stent geometry allows both longitudinal flexibility of the stent when the stent is constricted to its initial narrow diameter for threading through the body vessel, and maximum rigidity, after the stent is expanded to its final large diameter, for supporting the body vessel wall. The geometry of the stent is further designed to allow the stent to remain substantially the same length before and after expansion and even zero strain on the connection points.

Moreover, as will be described below, the stent geometry allows a substantially homogeneous distribution of strain on the stent material. This allows for less local strain (e.g. on the connection points securing neighboring radial rings of the stent to longitudinal segments and forming the rings themselves), and thus a smaller stent profile is achieved. It aids stent delivery, inside body tubes. Also, the less material used for the stent, the less rejection of the body to the foreign material. This geometry of the stent also allows a further diameter expansion by material stretching such as tantalum which allows up to about 40% elongation. The stent's further expansion is better achieved by the homogeneous distribution of stress, a result of the new geometry.

FIG. 1 shows a cylindrical stent with orthogonal cylindrical coordinates (R,θ, Z). Coordinate Z corresponds to the longitudinal central axis of the stent. When Z=0, the stent's longitudinal end is described. The stent length, its longitudinal axis, is Z. Radius r refers to the radius of the stent from the longitudinal axis of the stent to the outer circumference of the stent. Radius r, of course, changes with stent dilation during deployment of the balloon or other expansion of the stent radius by another mechanism (e.g., memory metal). As shown in FIG. 14, the stent 30, in its constricted state (i.e. before expansion), is a hollow cylinder, or is tube-like. The hollow cylinder has windings 31 on its surface joined together at points to form the radial rings. The stent has longitudinal flexibility, when in its constrained diameter, and allows for radial expansion. As shown in FIG. 15, the stent 30, in its expanded state, has the radial rings opened, the windings uncurl from their constricted to their expanded state, providing a larger radius r for the hollow cylinder of the stent construction.

FIG. 2 shows adjacent radial rings (1) and (2) of a stent. In the Figure (and in all of FIGS. 2–11) each ring is shown without the longitudinal connections which are provided between adjacent rings. The longitudinal connections are shown, for example, in FIGS. 14–16. Radial rings (1) and (2) are each originally, i.e., before expansion, curved, with the curves of the rings crossing the Z= constant axis of the ring. Each curved ring has dots or points (e.g. dot or point (3) on ring 1, and dots or points (4), (5) and (6) on ring 2, on its curves During outward expansion of the stent, dots (5) and (6) rotate. During the rotation of the dots, no deformation occurs in the dots. During expansion, dot (5) rotates in a 45° angle clockwise manner and dot (6) rotates in a 45° angle counterclockwise manner, thereby resulting in stent geometry shown in FIG. 3.

FIG. 3 shows two radial rings 1 and 2 of FIG. 2 after maximal stent diameter expansion. Although the connections on the longitudinal axis are not shown in the Figure, the resulting shape of the connected radial rings, after maximal expansion, is a cylindrical mesh of rectangular boxes (similar to screening material). A hollow cylinder of rectangular boxes is formed. The rectangular mesh can be seen by reference to FIG. 15.

As shown in FIGS. 4, 5 and 6, stents are depicted formed of rings 1 and 2 with dot rotation angles of 90°, 180°, and 360°, respectively, (and by the same principle, any intermediate angle) thereby achieving different levels of radial expansion.

In FIG. 7, the angle of rotation of the rotating dots is 45° clockwise (11) and 90° counterclockwise (for connecting dot 12).

In FIG. 9, it is shown that, in addition to achieving rotation around rotation dots or points at any radial line (Z1, Z2, . . .), it is also possible to rotate each ring in the opposite direction of rotation of its neighbor ring, i.e. like mirror images. Dots (14) and (16) will rotate counterclockwise while dots (15) and (17) will rotate clockwise. Again, flexibility of stent design is achieved.

In FIG. 10, a stent design is shown (four rings without ring interconnects for ease of illustration), as in FIG. 2, but having an angle of rotation or offset between the radial rings along the stent's longitudinal axis Z. FIG. 27 shows an embodiment of the invention where adjacent rings have their "peaks" and "valleys" in phase with one another while FIG. 28 shows an alternate embodiment of the invention where the rings are arranged in pairs with each ring of the pair is the mirrow image of the other ring of the pair, i.e., the "peaks" and "valleys" of the rings are 180 degrees out of phase. Of course, according to the present invention, the offset between adjacent of pairs of rings can incrementally vary from a low of 0 degrees, as shown in FIG. 27 to a high of 180 degrees, as shown in FIG. 28.

FIG. 11 shows, instead of having close radial loops as in FIG. 2–10, the present invention can also be practiced with a coil shape on which all rotation dots will be on the line that Z=K×θ.

In FIG. 12, ring 20 is circumferentially longer than the distance between two rings Z1 and Z2 (distance between

adjacent rings), and has shape 21 left side of FIG. 12) after stent expansion, leaving the stent length substantially unchanged. Longitudinal connector 22, whose length is equal to the distance between the two rings, does not deform during stent expansion. Connection 24 is a curved shape before stent expansion, and changes to a straight line 25 after stent expansion. The longitudinal connections can be between two dots (27 and 28) that are not necessarily placed along a line that is parallel to the Z axis.

FIG. 13 shows that for longitudinal flexibility (important for stent deployment to the site) segments of longitudinal connectors 30 and/or sections of the rings 31, can be selectively omitted for some parts of the stent.

FIGS. 14 and 16 show two embodiments of the stents, in accordance with the present invention, each in a constricted configuration. As shown, the radial rings 33 are connected with longitudinal connectors 35. In FIG. 14, the longitudinal connectors are straight (both before and after expansion), while in FIG. 16, the longitudinal connectors are curved (before expansion). FIG. 15 shows the stent 30 of FIG. 14 in an expanded configuration, after inflation by a balloon. FIG. 17 (not to scale) similarly depicts the expanded configuration of the stent of FIG. 16. As can be seen from the Figures, expansion of the stent allows the flexible, constricted configurations to be transformed into a cylinder comprised of substantially rigid rectangular grid geometry. The expanded stent is in the form a hollow tube. Consequently, the stent can be threaded through a body vessel in a flexible, constricted state, and subsequently expanded into a substantially rigid, expanded state for scaffolding against the body vessel wall.

FIGS. 18 and 19 show an embodiment of the stent where joints 38 (between adjacent rings and also forming the rings from straight segments) are circular rather than single connecting dots or points. As shown in the Figures, ring segments 32 (the arrows at the top of the Figure show the direction of stent expansion) and longitudinal connectors 35 are connected at circle joints 38. FIG. 18 shows the stent in a constricted configuration, prior to expansion, while FIG. 19 shows the stent after expansion. Points A–K represent connection points at which the radial ring segments 32 and longitudinal connectors 35 meet the joints 38. Comparing FIGS. 18 and 19, expansion of the stent from a constricted to an expanded configuration causes rotation of the connection points A–K to yield a rectangle-like mesh, in which the corners of the rectangles are occupied by the circular joints. Of course, as discussed, the mesh is in the basic hollow cylinder shape.

FIGS. 20A and B, 21 and 22 show three embodiments of the stent with undulated or highly curved radially oriented segments 65. In this embodiment, the undulations are opposed, offset U-shapes. Again, the direction of stent, radial expansion is shown on the Figures. FIGS. 20A and 20B, as well as 21 show two differing embodiments of circular or extended joints 68 (FIG. 21 shows hollow circle joints), while FIG. 22 shows a joint 69 which is a point-like intersection of stent ring segments and longitudinal elements. In these embodiments, stent expansion is achieved by rotation of the joints 68 and 69, and by consequent straightening of the undulated or highly curved, radially oriented segments 65. These embodiments allow excellent radial force and tissue scaffolding with minimal shortening along the stent's longitudinal axis. They also allow substantially homogeneous distribution of stress during expansion, with minimal stress and strain on the joints. FIG. 22 shows that every other ring is similar in geometry and thickness to every other ring with adjacent rings having different geometries and material thickness. Of course, the rings of the same geometry and material thickness can either be in phase, with its "peaks" and "valleys" or offset up to about 180 degrees, as shown in FIGS. 27 and 28.

In addition to the improvements provided by the new stent geometry described herein, use of a material such as tantalum can be particularly advantageous. Elongation of tantalum by applying radial expanding balloon pressure can achieve up to a 40% elongation of the stent material. Thus, this elongation of the stent material itself is in addition to the stent radial dilation which can be achieved from expansion of the novel stent by balloon expansion.

As shown in the drawings, the rotation points of the present stents enable large stent expansion, without creating high stress concentration on the connecting points of the stent. This is a significant improvement over both the Palmaz stent and the Pinchansik and Wolff stents of the prior art, in which stress concentration, followed by fatigue and corrosion, at any point, is a potential problem.

Similarly, it is also shown from the descriptions and the Figures that the stent is flexible, longitudinally, when constricted to a small diameter, and becomes stiff, only after expansion. This is also an important improvement over the prior art, as the present stent is not composed of alternating, rigid and articulated components, joined together, but rather is integrally constructed as a single flexible stent, having a long length, and having the ability to bend, homogeneously, along its longitudinal axis when in its constrained form.

Fabrication of the stents shown in FIGS. 1–22 can be accomplished in numerous manners. Two new methods and systems for manufacture of the stents are however, shown in FIGS. 23 and 24.

One current method for fabrication of a patterned etched cylinder is to form a wire mesh from a flat planar surface and then to fuse its two opposite edges to create a cylinder. That method, however, suffers a basic disadvantage in that the presence of the fusing line creates a weakened area along the longitudinal axis of the stent, which is potentially subject to fatigue and breakage. It would be preferable for the stent to be formed from a more uniform piece of material to avoid this potential problem.

According to the present invention, there is, therefore, provided two novel alternative methods for imaging the desired pattern i.e., the location of points, undulating connectors, ring and connecting segments, etc. onto a cylinder, without the need of fusing into a cylinder after forming of the design. Either a film contact imaging method or a laser scanning system can be used to accomplish this objective.

As shown in FIG. 23, a film contact imaging method is constructed using an elliptical mirror 100 which reflects ultraviolet light from an ultraviolet light source 110. The ultraviolet light source is located at one focal point of the elliptical mirror 100 and illuminates through a slit or narrow aperture 120 (which eliminates scattered light). Slit or aperture 120 is located at the other focal point of the elliptical mirror to allow for high density power illumination from the ultraviolet source. Rays of ultraviolet light 115 are thus reflected off of elliptical mirror 100 to pass through slit or aperture 120 and onto a moving film 130. Slit 120 extends parallel to the longitudinal axis of hollow tube or cylinder 140. Film 140 carries the design sought to be provided to the tube or cylinder 140.

Film 130 is in contact with hollow cylinder 140. FIG. 22 shows a drawing of the photoetching film for the stent production, according to the method of the present inven-

tion. Hollow cylinder **140** is material which is fabricated into the stent of the present invention. Film **130** serves as a mask or template, being transparent to ultraviolet light in some areas and opaque to ultraviolet in others in the predefined stent pattern. Cylinder **140** is coated with an appropriate material (a photoresist) for a photo-etching process. As ultraviolet light **115** is transmitted onto film **130** through slit **120**, film **130** moves past cylinder **140** while the cylinder **140** rotates. The rotation of the cylinder **140** is correlated with the movement of the film **130** to appropriately image the pattern on the film around and onto the cylinder **140**. As a result, ultraviolet light **115** passing through UV-transparent portions of the film template will strike the cylinder **140** in the desired pattern to photoetch the appropriate configuration onto cylinder **140**. An acid treatment is then used to remove the areas which were struck by the UV light. In general, the chemical aspects of the system are similar to that used in the manufacture of computer chips i.e., photoresist, masking, acid, etc.

It should be pointed out that variations on this design can, of course, be accomplished by those of ordinary skill in the art. For example, in the presence of a sufficiently high powered light source, usage of an elliptical mirror is not essential.

As shown in FIG. **24**, a second method which can be used for the fabrication of stents is a laser scanning system. The system consists of a cylinder or tube **160** to be etched, a laser **170**, the laser optics **180** (containing beam components and modulator), and a dynamic deflector **190** (such as a rotating mirror, a polygon, or any other known scanning deflector). The system is based upon a well-known flat bed scanning system. Cylinder **160** is coated with a photoresist, or material suitable for photoetching. A laser **170** is selected of the appropriate power and wavelength suitable for stimulating the photoresist in use. For example, for an ablation method, the laser can be a high powered IR laser diode; for a photoresist sensitive to visible light, the laser can be a laser in the visible range or for a conventional UV photoresist, an Eximer laser or third (or higher) harmonic generation Nd:YAG/Nd:YLF laser can be used. The laser beam is shaped by an appropriate optical system, and modulated by direct modulation in the case of an IR laser diode, with AOM (an Acoustic Optical Modulator) in the case of a CW laser in the visible, or by a vibrating mirror in the case of a UV laser.

The laser beam from laser **170** hits a deflector device **190** which can be a rotating mirror, a polygon mirror, or other known scanning device. The beam emerges from the deflector, passing through a scan lens **195** and focussed on the cylinder **160**. The cylinder, coated with a photoresist, rotates about its longitudinal axis **200** at a constant angular velocity, while the beam scans back and forth. The modulation of the laser beam allows writing a computer imaging file directly on the cylinder without the need of intermediate media (e.g. film). The laser scanning velocity is correlated to the cylinder angular velocity, and is determined by the energy required for exposure of the photoresist.

FIGS. **25** and **26** relate to use of the present invention as a stent graft. This is a stent over which a cloth sleeve is positioned to prevent blood from going through the stent wall or for having better support of the vessel wall. As a particular embodiment, the stent graft is in a Y-shape for the treatment of aortic aneurysm, near the aortic bifurcation. In such cases, simple tube stent grafts tend to migrate downwardly. In the Y-shape of the present invention, however, the stent is supported on the bifurcation and thus it cannot migrate from the site. A method of percutaneous insertion of this Y-stent graft is shown in the drawing. As shown in the drawings, the main tube integral with a right and a left tube, thereby forming the Y-shape stent graft. A first balloon passes from the left tube into the main tube while a second balloon passes into the right tube. During deployment, the right tube moves flexibly to the right. The second step of deployment contemplates the pulling of the entirety of the stent graft so that it is located and fixed to the aortic bifulcaton. Then inflation of balloon No. 1 for the main tube is accomplished. Then balloon No. 2 is inflated in the right tube. Then balloon No. 1 is pulled and reinflated followed by a withdrawal of balloons. FIG. **25** shows the Y-shaped tube stent graft in its open or expanded configuration. Balloon No. **1** is shown inflated and located in the main graft tube. Balloon No. **2** is shown in the right graft tube. Pulling balloon No. **1** and reinflating the same expands the left graft tube.

Having described this invention with regard to specific embodiments, it is to be understood that the description is not meant as a limitation since further variations or modifications may be apparent or may suggest themselves to those skilled in the art. It is intended that the present application cover such variations and modifications as fall within the scope of the appended claims.

I claim:

1. A medical stent, comprising:

at least two radial rings, each of said rings being curved into peaks and valleys, and further having windings, each of said rings having both a constricted state and an expanded state corresponding to the constricted and expanded state of said windings of said stent, said constricted state being a state of said rings in which said windings are curled in shape, said expanded state being a state of said rings in which said windings are straightened such that each of said rings becomes substantially circular and of greater diameter than said ring in said constricted state; and,

longitudinal connectors, said longitudinal connectors being connected to said radial rings at rotatable joints, each of said rotatable joints being located approximately midway between the tops of said peaks and the bottoms of said valleys, said longitudinal connectors connecting said radial rings to form said stent in a cylindrical shape, said stent being flexible along substantially its entire longitudinal axis when said stent is in said constricted state, said stent being substantially rigid when said stent is expanded to said expanded state, and said stent being at least substantially the same length whether said stent is in said constricted state or in said expanded state.

2. A medical stent as claimed in claim **1**, in which said rotatable joints are substantially larger than direct connections between said longitudinal connectors and said radial rings.

3. A medical stent as claimed in claim **1**, wherein said stent is expandable by a balloon catheter.

4. A medical stent as claimed in claim **1**, wherein said rings have points on said windings, said points rotating forty-five (45) degrees upon expansion of said rings from said constricted state to said expanded state.

5. A medical stent as claimed in claim **1**, wherein said rings have points on said windings, said points rotating ninety (90) degrees upon expansion of said rings from said constricted state to said expanded state.

6. A medical stent as claimed in claim **1**, wherein said rings have points on said windings, said points rotating one hundred and eighty (180) degrees upon expansion of said rings from said constricted state to said expanded state.

7. A medical stent as claimed in claim 1, wherein said rings have points on said windings, said points rotating three hundred and sixty (360) degrees upon expansion of said rings from said constricted state to said expanded state.

8. A medical stent as claimed in claim 1, wherein said rings have at least two points on said windings, at least one of said points rotating forty-five (45) degrees in a first direction and at least one of said points on said same ring rotating ninety (90) degrees in a direction opposite to said first direction.

9. A medical stent as claimed in claim 1, wherein said stent comprises coupled pairs of adjacent rings, each of said pairs comprising a first ring and a second ring, the winding of said first ring in said pair being the mirror image of the winding of said second ring in said pair about a plane located between said coupled pairs of adjacent rings.

10. A medical stent as claimed in claim 1, wherein said longitudinal connectors are substantially straight when said stent is in said constricted state.

11. A medical stent as claimed in claim 1, wherein said longitudinal connectors are substantially straight both when said stent is in said constricted state and when said stent is in said expanded state.

12. A medical stent as claimed in claim 1, wherein said longitudinal connectors are curved when said stent is in said constricted state, and become straight when said stent expands into said expanded state.

13. A medical stent as claimed in claim 1, wherein all of said rings are not fully circular as a consequence of at least one segment of at least one of said rings being omitted.

14. A medical stent as claimed in claim 1, wherein the shape of said stent in said expanded state is a hollow cylinder of substantially rigid rectangular mesh.

15. A medical stent as claimed in claim 1, wherein said rotatable joints are circular.

16. A medical stent as claimed in claim 1, wherein said rotatable joints are circular and hollow.

17. A medical stent as claimed in claim 1, wherein at least some of said rings comprise undulating segments.

18. A medical stent as claimed in claim 17, wherein said undulating segments are opposed and radially offset U-shapes.

19. A medical stent as claimed in claim 1, wherein at least some of said longitudinal connectors comprise undulating segments.

20. A medical stent as claimed in claim 19, wherein said undulating segments are opposed and circumferentially offset U-shapes.

21. A medical stent as claimed in claim 1, wherein said rings comprise at least a first ring and a second ring, and wherein said peaks and said valleys of said first ring are radially offset with respect to said peaks and said valleys of said second ring by greater than 0 to about 180 degrees.

22. A medical stent as claimed in claim 1, in which at least part of said stent is comprised of tantalum.

23. A medical stent as claimed in claim 1, wherein radial expansion of said rings can be accomplished, at least in part, by mechanical strain.

24. A medical stent as claimed in claim 1 wherein radial expansion of said rings can be accomplished by both uncurling of said windings and mechanical strain.

25. A medical stent as claimed in claim 1 comprising a Y-shaped stent graft.

* * * * *

EXHIBIT O

From Bench to Bedside

Intracoronary Stenting

From Concept to Custom

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When Charles Stent, a 19th century English dentist, developed a mold with which to form an impression of the teeth and oral cavity, he would never have imagined that his name would become synonymous with the management of obstructive vascular disease, in particular coronary artery disease (Fig 1).[1] The term "stent" became associated with a device that held a skin graft in position, a support for tubular structures that were being anastomosed, and, more recently, an endovascular scaffolding to relieve and prevent vascular obstructions.

The management of coronary atherosclerosis has shifted from "masterly inactivity" to medical therapy, coronary bypass surgery, and, more recently, percutaneous techniques introduced by Gruentzig et al in 1977.[2] Intracoronary stenting with continuing refinements appears poised to become the mainstay of the mechanical treatment of obstructive coronary disease.

Preclinical Evaluation

In his 1912 Nobel lecture, laureate Alexis Carrel described experiments with glass and metal tubes covered with paraffin that were introduced into canine thoracic aortae. Coagulation did not occur provided the aortic wall was not ulcerated, with one animal surviving for 90 days with a glass tube. He concluded that the presence of foreign bodies within vessels did not necessarily produce thrombus.

The concept of using an implantable prosthetic device to maintain the luminal integrity of diseased vessels was reintroduced by Charles Dotter in 1964, when he suggested that the temporary use of a silicone elastomer endovascular splint could maintain an adequate lumen after the creation of a pathway in a previously occluded vessel.[3] In 1969, he reported the results of the nonsurgical endarterial placement of spiral springs, mounted coaxially on a guidewire and positioned with a pusher catheter in the femoral and popliteal arteries of healthy dogs.[4] Although these early stents were able to be positioned satisfactorily, secondary dislocations occurred because only small devices could be used, and significant narrowing within the stents occurred. These findings appeared to suppress any optimism that such a device might have a role to play in atherosclerotic vascular disease, until the early 1980s, when Dotter et al[5] presented the work of further canine experiments with a modified stent. Dotter placed coils made of the "memory metal" nitinol in peripheral vessels and injected heated saline solution through the catheter, allowing the coil to enlarge to its predetermined form with a luminal diameter approximately equal to that of the adjacent blood vessel. He suggested that this device might be of potential therapeutic use not only in arteries and veins, but also in the cerebral aqueduct, bladder neck, biliary system, and tracheobronchial tree. Initial experiments with this stent in nonheparinized dogs proved promising, with no episodes of subacute thrombosis, and vessel patency was maintained at 4 weeks.[6]

The potential for the use of such a device in the nonsurgical treatment of vascular disease had become evident, and experimentation with a variety of innovative devices had commenced. Maass and coworkers[7] reported the results of implantation of spiral springs in the aortae and vena cavae of dogs and calves. When torque was applied, the springs decreased in diameter, allowing distal delivery, and on release of the torque, they expanded to their predetermined dimensions.[7] Although the spirals remained stable and did not produce stenosis, thrombosis, or perforation, target lumen access remained a limitation. An expanding zigzag-shaped stainless steel stent was developed by Wright and coworkers, and the results of initial studies in dogs were reported.[8] It was appreciated that the diameter of the fully expanded stent had to be larger than the recipient vessel to prevent migration.[8] The above devices were all reliant on the inherent recoil properties of the metal used, which, on release or positioning, returned to a predetermined diameter, desirably a little greater than the vessel proximal and distal to the treated segment (Fig 2).

The concept of a stent mounted on a balloon was introduced by Palmaz. In 1985, he described the initial results of implantation of a woven stainless steel graft mounted on angioplasty balloon catheters and placed in the aortae and peripheral arteries of dogs by balloon expansion[9] (Fig 2). The following year, Palmaz et al[10] published the data of an extended group of 18 balloon expandable stent implantations and provided a unique and accurate insight into the problems that would torment stent implantation for the subsequent decade. Stents were placed in the iliac, femoral, renal, mesenteric, and carotid arteries of normal dogs via arteriotomies. Procedural heparinization was used without long-term anticoagulation or antiplatelet therapy only in the last 9 cases. Four thrombotic occlusions oc-

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FIG 1. Charles Stent (1845-1901), an English dentist who lent his name to a tooth mold (bottom) and more recently to endoluminal scaffolding devices.

cured, all in nonheparinized animals, and thus motivated the use of heparin in the latter experiments. Palmaz recognized that "heparin does not prevent occlusion of grafts with low flow and the best results were obtained in those without flow restriction,"[10] a canon of contemporary stenting. Additionally, the overall stent patency at 35 weeks was 77%, giving a restenosis rate of 23%, a prelude to the findings of more recent studies.

With refinement and miniaturization of equipment, smaller and more distal vessels could be accessed, and stents began to be implanted in the coronary system. Rousseau and coworkers[11] developed and tested a flexible, self-expanding stainless steel mesh tube, restrained by a sheath. Forty-seven devices were implanted in 28 dogs, 21 in the coronary arteries, without the use of anticoagulation or antiplatelet agents. Partial or total thrombosis was seen in 8 of 28 animals (29%), which was partly attributed to the earliest of several models of prostheses used during the study. Thrombosis was recognized to occur at points of rapid reduction of vessel diameter, when the end of the prosthesis was engaged in a side branch of a major vessel and when there was a high ratio of unconstrained to implant device diameter.[11] It was found that the process of endothelialization, incorporation of the stent into the vessel wall by neointimalization, had occurred by the third week after implantation, consistent with the findings of others.[8,9] These results, particularly in the second part of the series, which predominantly involved implantation in coronary arteries, primed this group of investigators for the beginnings of stent implantation in human atherosclerotic vessels.

Interest in stent implantation in human coronary arteries intensified after reports of successful implantation of balloon-expandable stents in canine coronary arteries. Schatz et al[12] reported the results of percutaneous implantation of 20 Palmaz-type stents, and Roubin et al[13] described implantation in 39 animals of a new interdigitating flexible coil stent mounted on a balloon. With the appearance of these reports in *Circulation* in 1987, the divorce of coronary stenting from vascular radiology had occurred.

Clinical Development

With the hope that the two problems that continued to trouble coronary balloon angioplasty, namely, acute occlusion and restenosis, could be alleviated or at least attenuated, Jacques Puel in Toulouse, France, and, shortly afterward, Ulrich Sigwart in Lausanne, Switzerland, implanted the first stents in human coronary arteries in the spring of 1986. The results of implantation of 24 self-expanding mesh stents (Medinvent) in 19 patients (17 restenosis, 4 acute closure, and 3 venous bypass grafts) were reported subsequently.[14] Three complications (15.8%) related to stent thrombosis occurred. No cases of restenosis were observed within the stented segment 9 weeks to 9 months after implantation. By early 1988, 117 Wallstents, as these self-expanding stents became known, had been implanted in the native coronary arteries (94 stents) or saphenous bypass grafts (23 stents) of 105 patients. The results were daunting, with complete occlusion of 27 stents occurring in 25 patients, resulting in controversy and a diversity of anticoagulation regimens. However, with the expectation that a solution to the problem of thrombotic occlusion would be found, optimism in the future clinical utility of the technique remained, because the rate of restenosis in those stents that were patent at follow-up was 14%.[15]

The early clinical implantation of coronary stents remained largely limited to situations of acute and threatened closure after balloon angioplasty, with a diminishing proportion of patients proceeding to semielective coronary bypass surgery. Roubin and coworkers[16] reported the results of Gianturco-Roubin stent implantation in 115 patients with acute or threatened closure in 119 vessels in the years 1987 through 1989. Stenting produced an optimal result in 93% of the cases. Given the emergent nature of the procedure, the number of complications was acceptably low, with a hospital mortality rate of 1.7%, a bypass surgery rate of 4.2%, an overall myocardial infarction rate of 16%, and a subacute stent thrombosis rate of 7.6%.[16] Although it appeared that the stent had come to the rescue in the acute closure situation, a restenosis rate of 41% was observed in those patients (76%) who had undergone restudy at the time of publication of the study, indicating that the long-term solution had yet to be found.

During the same period (1987 through 1989), Schatz maintained a multicenter registry of elective Palmaz-Schatz stent implantations in native coronary arteries. Delivery of the device was successful in 213 (94%) of 226

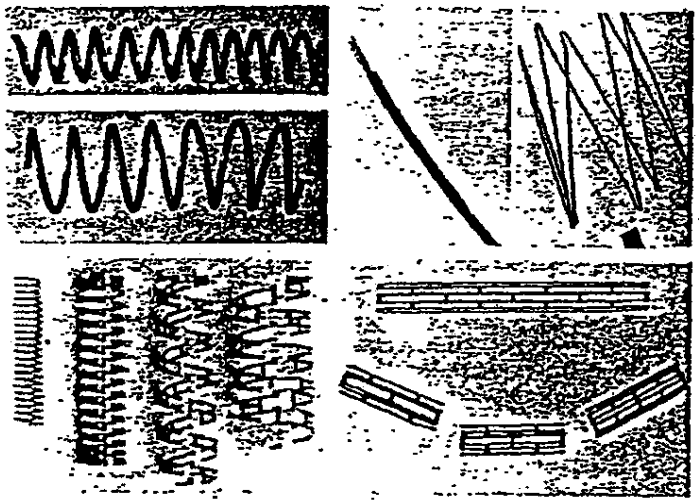

Fig 2. Four early endovascular stents. The upper left panels show Dotter's early nitinol coil wire stent compacted for placement and after heat-induced expansion to its predetermined dimensions.[6] The zigzag expanding stainless steel stent described by Wright et al[8] shown in the upper right panels in both its sheathed and unsheathed forms. The lower left panel shows the stents developed by Maass et al.[7] The lower right panel shows the balloon expandable stainless steel Palmaz stent.[9]

attempted lesions.[17] Early optimism that this stent was less thrombogenic than others,[18] and thus required little if any anticoagulation therapy, was quashed when a subacute closure rate of 16% was observed in the first group of 39 patients who received only aspirin and dipyridamole after the procedure. In addition, the second group of 174 patients received warfarin for 1 to 3 months, with a dramatic reduction in subacute thrombotic stent occlusion to 0.6%.[17] One must question whether patients were even more carefully selected after the discouraging findings in the first group of patients. Nevertheless, the notion was being entertained that the complication rates and perhaps even the long-term results of elective stenting were significantly less than those obtained after the bailout situation, in which the artery had undergone multiple and often prolonged dilations.

The role of stenting a restenotic lesion after a previous balloon angioplasty was also being explored. The Wiktor stent, a single interdigitating tantalum wire, was implanted in 50 consecutive patients with restenosis as part of a European registry. The implantation success rate was 98%. Acute or subacute occlusion occurred in 5 patients (10%), and restenosis according to the ≥50% diameter criterion was observed in 13 patients (26%) 5.6±1.1 months after stent implantation.[19]

A number of fundamental questions were raised by the findings of these and other studies. Were the variable results from the growing number of stent registries related to the clinical situation (elective versus bailout stenting), the inherent properties of the device, the deployment strategy, or the anticoagulation regimen? The characteristics the ideal stent should possess had become clear (Table 1). The feeling of excitement surrounding the use of stents in obstructive coronary disease, despite the hurdles, prompted Spencer King III to ask a number of searching questions.[20] Was there a problem for which stenting could provide a solution? Was the proposed stenting strategy efficacious? Was stent implantation safe? Could stents be made sufficiently foolproof for widespread clinical use? It was clear that countless questions remained and that thousands of patients had to be studied carefully before the clinical domain of intracoronary stenting could be clearly defined.

TABLE 1. Desirable Stent Characteristics

Flexibility
Trackability
Low profile
Visibility
Thromboresistance
Biocompatibility
Reliable expandability

Randomized Trials

Two landmark randomized trials have been performed and reported,[21,22] perhaps once and for all determining the fate of coronary stent implantation. The European-based Benestent and the North American–based STRESS studies both began patient recruitment in 1991. In both studies, patients were randomized to receive conventional balloon angioplasty or Palmaz-Schatz stent implantation in a primary lesion of a native coronary artery with a diameter stenosis of 50% and 70% in the Benestent and STRESS studies, respectively. The target lesion was required to be <15 mm long and the reference diameter ≥3 mm. The presence of thrombus, ostial stenosis, a lesion spanning a major bifurcation, diffuse disease, severe tortuosity, and abnormally functioning myocardium subtended by the lesion, along with intolerance of anticoagulants and ineligibility for coronary bypass surgery, were exclusion criteria. Five hundred sixteen patients (257 balloon and 259 stent), all of whom had stable angina, were recruited in the Benestent study and 407 patients (202 balloon and 205 stent), of whom 47% had unstable angina, were randomized in the STRESS study.

The incidence of restenosis according to the 50% diameter stenosis criterion and a per protocol basis was significantly lower after stent implantation (Benestent, 22%; STRESS, 32%) than after balloon dilation (Benestent, 32%; STRESS, 42%) and was associated with a more favorable long-term clinical outcome in patients who received a stent. The 7-month event-free survival was 79.9% and 70.4% after stenting and balloon dilation, respectively, in Benestent ($P<.05$) and 80.5% and 76.2%, respectively, in the STRESS study (P=NS). This was largely because

of a reduced need for reintervention in the stented group. The 1-year follow-up of the Benestent patients has subsequently been published[23] and shows a continued benefit for stented patients, with a 1-year event-free survival of 76.8% compared with 68.5% in the balloon angioplasty patients. Of the 12 additional events that occurred between 7 and 12 months (8 in the stent group and 4 in the balloon group), 8 involved a revascularization procedure.[23]

The STRESS investigators also reported a superior procedural success rate in the stent group (stent, 96.1%; balloon, 89.6%). There was no significant difference in acute closure or stent thrombosis between the two treatment groups in either study. These encouraging results were at the cost of significantly increased bleeding and vascular complications and a longer hospital stay in those patients who received a Palmaz-Schatz stent. The clinical results of both trials are displayed in Table 2. In addition to these two multicenter trials, enrollment in the Spanish START (STent versus Angioplasty Resienosis Trial) trial continues. A total of 564 patients with stable angina pectoris and a new native coronary artery lesion will be randomly allocated to balloon angioplasty alone or Palmaz-Schatz stent implantation, with the primary end point being the 6-month restenosis rate. The results, when available, are expected to provide data complementary to those of the Benestent and STRESS studies, which have demonstrated a reduced restenosis rate, an improved event-free survival, and an abrupt occlusion rate similar to that of balloon angioplasty but an unacceptable incidence of bleeding and vascular complications, urging the next generation of stenting trials.

Perhaps one of the most promising developments is the design of stents with improved thromboresistant properties,[24] thus alleviating the need for systemic anticoagulation therapy and thereby reducing, if not abolishing, bleeding and vascular complications. In the pilot phase of the Benestent II trial, 207 patients in four equal groups received a heparin-coated stent, with an increasing delay to the commencement of anticoagulation therapy of up to 36 hours after implantation. There were no episodes of acute or subacute occlusion, and the overall 6-month restenosis rate was 13%.[25] On the basis of these compelling results, the Benestent II trial has commenced. Eight hundred twenty-four patients with primary coronary artery lesions in a native vessel will be randomized to receive a heparin-coated Palmaz-Schatz stent, followed by treatment with aspirin and ticlopidine, or conventional balloon angioplasty. A subrandomization will occur to allocate patients to only clinical or clinical and angiographic follow-up. Additionally, a detailed account will be kept of the medical costs related to coronary artery disease in all patients. This trial aims to prove that primary coronary stenting not only will reduce the rates of subacute occlusion and restenosis and improve event-free survival but also will reduce the economic burden of a coronary intervention on society and its psychosocial burden on the individual patient.

The role of stenting for acute or threatened vessel closure after coronary angioplasty has also been studied in a randomized fashion. Much of the early stenting experience was for bailout after failed balloon angioplasty, usually with restoration of normal coronary flow and resolution of chest pain and ECG changes.[14] It appeared that patients fared favorably after bailout stenting compared with emergency bypass surgery or conservative management.[26] However, a more recent case-control study[27] revealed that the clinical outcome after bailout stent implantation was no better than conventional treatment despite rapid restoration of blood flow and a good angiographic result. Bailout stenting has also been identified as one of the most powerful independent predictors of subsequent subacute stent thrombosis.[28] One should bear in mind that in these earlier studies, bailout stents were often implanted after closure proved to be refractory to prolonged attempts at therapy with various modalities including autoperfusion balloons and thrombolytic agents.

To test the efficacy of stenting in this situation, at least three studies randomizing stents against balloons have been performed. In the Stent-by and TASC-II (Trial of Angioplasty versus Stenting in Canada) studies, the utility of Palmaz-Schatz stenting was compared with prolonged balloon angioplasty methods, whereas in the GRACE (Gianturco-Roubin Stent Acute Closure Evaluation) study, a Gianturco-Roubin stent was used. Despite sound protocols, these studies have been hindered by slow recruitment and dilution of results by crossover. It appears that the use of and faith in the stent in the bailout situation is so strong that few interventionists are willing to subject their patients with acute or threatened closure to prolonged and repeated balloon dilation.

A further niche for stenting is in the increasing proportion of patients with aging saphenous venous bypass grafts who return for repeat coronary revascularization. Stent implantation appears to be an attractive option with a high chance of immediate success, an acceptable complication rate, and a favorable late clinical outcome (76.3% 12-month event-free survival) compared with previous bal-

TABLE 2. Clinical Results of the Benestent and STRESS Studies

	Benestent Study			STRESS Study		
	Balloon (n=257)	Stent (n=259)	*P*	Balloon (n=202)	Stent (n=205)	*P*
Composite clinical end-point analysis						
In-hospital period	6.2%	6.9%	NS	7.9%	5.9%	NS
At follow-up						
Half year*	29.6%	20.1%	<.05	23.8%	19.5%	NS
1 Year	31.5%	23.2%	<.05	---	---	---
Event-free survival						
Half year	70.4%	79.9%	<.05	76.2%	80.5%	NS
1 Year	68.5%	76.8%	<.05	---	---	---
Acute closure/stent thrombosis	2.7%	3.5%	NS	1.5%	3.4%	NS
Bleeding and vascular complications	3.1%	13.5%	<.05	4.0%	7.3%	<.05
Hospital stay, d	3.1	8.5	<.05	2.8	5.8	<.05

*Benestent, 7 months; STRESS, 8 months.

loon angioplasty studies.[29-31] The results of randomized studies comparing balloon angioplasty with stent implantation in bypass grafts are awaited to determine whether the growing trend to implant stents is justified.

Randomization of balloons versus stents has also been performed for restenotic lesions (the Rest study) and after recanalization of a coronary artery occlusion (Stenting in Chronic Coronary Occlusions [SICCO]). The results of these trials, when they become known, will give more direction to current clinical practice.

With the growing number of publications reporting the results of coronary stenting, generally with favorable results in comparison with balloon angioplasty, a frenzy of activity has pervaded the stent development industry. A diverse variety of stents are becoming clinically available, varying in composition, configuration, and size (Fig 3). Although niches for particular stents are evolving, the advantage of one stent over another may never be defined scientifically, and it is likely that market forces will be a major determinant of clinical choice.

The Flow and Ebb of Anticoagulation Therapy

From the very early animal studies, it became clear that implantation of endoprostheses within the vascular system activated coagulation, with resultant thrombosis of varying degree depending on stent composition, configuration, and size.

The finding that the thrombogenicity of metals was related to their surface properties, such as electric charge,[32] prompted studies of stents made from various metallic compounds in the hope that the ideal thromboresistant device would be found, with little success.[7,11,12] The reported variation of thrombosis within stainless steel stents was thought to be explained in part by configuration. Schatz was encouraged by his early canine studies with the balloon-expandable slotted-tube stent when no instances of thrombosis were encountered.[12] His optimism continued after implantation of the stent into the first 17 human coronary arteries. No episodes of abrupt closure occurred in these patients, who were given procedural dextran and heparin and discharged to receive aspirin and dipyridamole alone. However, as the series of patients grew, a significant number of thrombotic episodes occurred, and warfarin was added to the postprocedural regimen.[13] Thrombosis within the self-expanding Medinvent stent, which also was composed of stainless steel, was encountered in animal experiments,[11] prompting the use of intracoronary urokinase along with heparin, aspirin, dipyridamole, and coumadin in the first coronary implants.[14] Despite this aggressive regimen, thrombosis remained a problem, and both dextran and sulfinpyrazone were added.[15] The escalation of anticoagulant regimens, with up to seven agents (aspirin, dextran, heparin, dipyridamole, sulfinpyrazone, urokinase, and coumadin) being used and associated bleeding and vascular complications, led to the inevitable question, "Are we the sorcerer's apprentice?"[33] and in many centers, stenting was temporarily abandoned except for bailout situations.

Some stalwarts wondered whether the problem of thrombosis was in fact as much related to the flow through the implanted stent, with adequate expansion, inflow, and outflow, as to the metallic properties of the stent itself, and

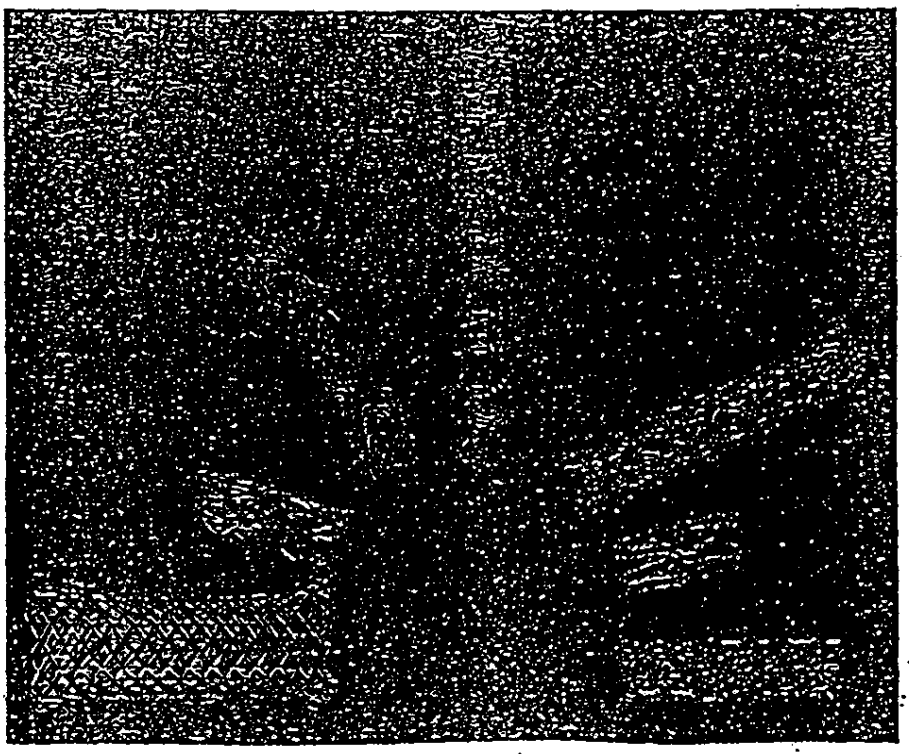

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Fig 3. Seven coronary stents, clockwise from bottom left: Wallstent, Palmaz-Schatz stent, Wiktor stent, Gianturco-Roubin stent, Cordis stent, AVE stent, and multilink stent.

they continued to implant stents electively, frequently in restenotic lesions.[36] With greater attention to optimal stent implantation in perhaps more carefully selected vessels, along with continued stringent anticoagulation therapy, the incidence of subacute occlusion diminished to <5%. Of particular interest was the rate of restenosis, which promised to be lower than that after balloon angioplasty, along with an improved event-free survival. In the Benestent and STRESS studies that ensued, the subacute thrombosis rates were 3.5% and 3.4%, respectively, with an anticoagulation/antiplatelet regimen consisting of dextran, heparin, aspirin, dipyridamole, and warfarin.[21,22]

The tide began to turn with the introduction of intracoronary ultrasound and high-pressure intrastent dilation to ensure optimal stent deployment.[35] The concept of high-pressure stent expansion, thought to be important by the pioneers of stenting, could be tried as a result of the development of balloon catheters able to withstand high pressures and tested with intravascular ultrasound. Anticoagulation regimens began to diminish with ticlopidine or even aspirin alone replacing warfarin and both dextran and dipyridamole being omitted completely without any apparent rebound in the rates of subacute thrombosis.[36-38] It appears paradoxical that these results can now be achieved without significant changes to the configuration and composition of the stent itself, strongly suggesting that meticulous attention to stent expansion and through flow plays a critical role in successful stent implantation. We are reminded of the words of Julio Palmaz, who made similar observations a decade ago.[10] Additionally, stent coatings have been studied, in particular covalently bound heparin. In the fourth phase of the Benestent II pilot study, 50 patients received a heparin-coated stent and were discharged to receive ticlopidine and aspirin with no episodes of subacute thrombosis.[25]

With the ebb of anticoagulation therapy, bleeding complications and the length of hospital stay have been reduced dramatically to equal those of balloon angioplasty. Continued development of coated and biocompatible stents and attention to optimal deployment will likely mean future postprocedural anticoagulation therapy will consist of aspirin alone.

Why Should We Stent?

To answer this question, we return to those raised by Spencer King III.[39] First, is there a problem for which stenting provides a solution? Balloon angioplasty has been hampered by two major limitations: acute closure and restenosis. Although the proportion of patients experiencing acute closure is small (2.7% and 1.5% in the balloon angioplasty groups of the Benestent and STRESS studies, respectively[21,22]), it is associated with a significant chance of myocardial infarction and death. As the number of patients with complex, diffuse, and multivessel disease increases, so will the chance of acute closure. The availability of more effective antiplatelet agents, thromboresistant stent coatings, and optimal stent deployment will continue to reduce the problem of stent thrombosis,[39] making stenting an attractive option. The Achilles' heel of coronary angioplasty remains restenosis, with ≈30% of lesions renarrowing because of recoil and intimal hyperplasia. This figure has remained static despite a multitude of pharmacological and mechanical attempts to reduce it. It has been suggested that patients should equate coronary angioplasty with dental treatment, regular and benign. But even a dental visit requires time off work, provokes anxiety, costs money, and has a risk of complications. This approach must be regarded as a temporary solution. While awaiting discovery of the "fluoride" of coronary artery disease, new strategies to reduce the rates of restenosis and associated repeated interventions must be sought. The suggestion that restenosis and related clinical event rates may be lower after stenting of primary coronary lesions, gleaned from early registries, has been confirmed by the Benestent I, STRESS, and Benestent II pilot studies,[21,22,25] convincing most practitioners that this problem can be alleviated at least in part by stenting.

Second, King asked, "Is the treatment worse than the disease," raising the issue of safety. In the editorial accompanying the Benestent and STRESS studies, Eric Topol provided some words of caution.[40] Although abrupt occlusion rates after stenting were not significantly higher than those after balloon angioplasty in both studies, the need for anticoagulation therapy resulted in significant and unacceptably high rates of bleeding complications in the stented groups (Benestent, 13.5%; STRESS, 7.1%), along with a prolonged hospital stay.[21,22] With the current use of intracoronary ultrasound and high pressure postdeployment dilation, warfarin has been successfully replaced by ticlopidine and aspirin or even aspirin alone,[25,37,38] maintaining an abrupt closure rate of <3% and reducing bleeding complications and hospital stay to equal those of balloon angioplasty. The introduction of smaller guiding catheters and miniaturization of interventional devices, which allow a smaller arterial puncture via the femoral and, more recently, radial artery approach,[41] although not without limitations, have also contributed.[24] The potential for other problems, such as metal fatigue, stent migration, and endarteritis, appears to diminish as time passes.

Finally, in an era of escalating healthcare costs, the cost-effectiveness of stenting must be considered. Both the Benestent and STRESS studies have shown a superior 6-month event-free survival in stented patients,[21,22] and this benefit has been found to be maintained beyond 1 year.[23] The economic impact has been negated in part by the expense of the stent itself, a prolonged hospital stay, and additional costs related to anticoagulation therapy and associated bleeding complications; however, with contemporary antiplatelet regimens, these problems clearly will decline. Furthermore, the cost of a primary stenting procedure is less than that of a bailout procedure both in terms of the amount of material used and subsequent complications.[28] A decision analytic model has been used to evaluate the potential cost-effectiveness of a new coronary intervention, and it was suggested that elective coronary stenting may be a reasonably cost-effective treatment for patients with single-vessel coronary disease.[42] The Benestent II trial will prospectively evaluate cost data and compare costs for patients randomized to stenting with those for patients allocated to balloon angioplasty. Additionally, one must consider not only the economic burden on society but also the psychosocial cost to the individual patient, for example, days off work, which can be lessened only by a reduced need for reintervention after stenting. We await the results of further studies.

The Future

Despite the major advances that have been made in coronary stenting over the past decade, this is merely the beginning. All registries and trials of elective stent implan-

tation have acknowledged a varying degree of selection, with inclusion and exclusion criteria, making generalization of the results to the general angioplasty population hazardous. The results of stenting diffuse, complex, and small vessels remain uncertain, if not unfavorable. In both the Benestent and STRESS trials, the mean reference diameter of the carefully chosen discrete lesions was 3.0 mm.[21,22] A meta-analysis of these trials has clearly shown that the rates of restenosis and clinical events are higher after stenting of smaller vessels. In stented vessels <2.6 mm in diameter, the 6-month restenosis rate was 38% compared with 22% in vessels <3.4 mm.[43] Although some clinics are stenting up to 50% of cases, it is likely that stenting is merited on scientific grounds in a far lesser percentage of their angioplasty population. Further research in a wider range of lesion types and clinical situations, along with continuing developments described below, must be undertaken to reduce the mismatch between evolving clinical practice and scientific foundation.

New Developments

All currently available stents are made of metal, and in every design, a compromise is made between scaffolding properties and flexibility. Metals induce a varying degree of thrombogenesis, necessitating anticoagulation or antiplatelet therapy, and induce significant intimal hyperplasia, both factors that discourage the use of stents in small vessels or in situations of diminished flow. Additionally, the long-term effects of a metallic prosthesis within the vascular system, although seemingly benign, are unknown.[40] Needless to say, the search for the ideal stent continues.

Animal work continues on varying the surface charge and texture of stents by galvanization and ion bombardment. Palmaz-Schatz stents coated with platinum, gold, and copper by these two techniques have been implanted in rabbit iliac arteries. It was found that thrombus formation occurred in stents coated by galvanization, which resulted in a higher surface porosity, and not in those treated by ion bombardment or those left uncoated. These processes also influenced the surface charge, with the most electropositive coatings (platinum and gold) inducing markedly less neointimal formation within the stent than copper, which was the least electropositive. Thus, it appears that the surface texture influences thrombogenicity, whereas neointimal hyperplasia is related to charge.[44] Although alteration of the coatings and charge of metallic stents appears promising, a relatively rigid device with associated limitations is retained.

Perhaps more exciting is the concept of stents made of materials that can be degraded or absorbed. The fibrin stent appears to have the advantages of being able to cover an angioplasty injury site and provide a healing matrix and may also be of value in vein grafts in which a membrane may prevent the distal embolization of friable material. Animal experiments have shown the fibrin film stent to be biocompatible and absorbable, and it appears to be safe without the use of anticoagulation therapy.[45] Uncertainty remains concerning its effects on neointimal proliferation and the immune system.

Another area of intense interest is polymer stents, which can be loaded with antithrombotic or antiproliferative agents (eg, methotrexate) in high concentration for sustained local delivery. Bioabsorbable polymers may also avoid the potential for late complications and thus have the potential to prevent elastic recoil, thrombosis, neointimal proliferation, and systemic side effects. The findings of a marked inflammatory response resulting in significant luminal encroachment after polymer stent implantation in early porcine experiments appear to have been overcome by the use of a stent comprising high-molecular-weight poly-L lactic acid.[46]

Finally, perhaps the most promising new field is that of radioactive stenting. The antiproliferative effect of ionizing radiation has been used for decades to reduce cancer growth and also to reduce the formation of keloid scars. Restenosis within stents is primarily caused by an intimal hyperplastic response due to vascular smooth muscle cell proliferation, and thus the use of a radioactive stent[47,48] or local preirradiation of the lesion before stent implantation appears to be an attractive concept. Porcine experiments have shown that preirradiation of the coronary segment to be stented with γ- and β-radiation significantly reduced neointimal hyperplasia.[49] Palmaz-Schatz stents, made radioactive by ion bombardment in a cyclotron, were implanted into the iliac arteries of rabbits and emitted predominantly β- but also γ- and x-radiation. Neointimal thickening was suppressed, and delayed stent endothelialization, depending on the radiation dose, was observed without an increase in stent thrombotic events.[48] The use of ^{32}P as a β-particle emitter appears particularly promising.[47] It ensures local radiation delivery, because the maximal range of β-particles is 3 to 4 mm in tissue. It has a desirable half-life of 14.3 days and is undetectable at 4 months. Additionally, it exposes the interventionist to less radiation than that of fluoroscopy scatter. The results of the first human trials are eagerly awaited.

Conclusions

Since the very beginning of interventional coronary techniques, the concept of a stent to scaffold stenotic lesions appeared logical and attractive. The problems of thrombogenicity of the metallic device and the need for anticoagulation therapy and resultant bleeding complications initially hampered its clinical introduction and development. With knowledge gained both clinically and from intravascular diagnostic techniques, it was realized that thrombosis was as much related to inadequate stent deployment and through flow as to the metallic composition of the stent. The rate of restenosis after stenting appeared to be low, particularly in primary lesions. Armed with this information, the first randomized trials were undertaken, providing results that have secured the future of stenting as a mainstay of interventional cardiology. With continued developments and refinements, stenting may well lead the coup of percutaneous transluminal angioplasty over surgical revascularization.

We look forward to the results of the first randomized trials of stenting versus surgical revascularization for multivessel coronary artery disease.

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KEY WORDS • stents • angioplasty • atherosclerosis • coronary disease

EXHIBIT P

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SCIMED LIFE SYSTEMS, INC., BOSTON SCIENTIFIC SCIMED, INC., BOSTON SCIENTIFIC CORPORATION and MEDINOL, LTD.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 99-904-SLR (consolidated)
JOHNSON & JOHNSON, CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS, INC.,	)	
Defendants.	)	

O R D E R

At Wilmington this 15th day of August, 2001, having heard oral argument on the papers submitted in connection with claim construction issues; and having reviewed the patents' drawings, specifications and claims with a view to ascertaining the invention;[1]

IT IS ORDERED that the disputed claim language in the '303, '120 and '018 patents, as identified in the papers, shall be construed as follows, consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit:

1. **The '303 Patent – Claim 6**

a. **"Stent."** A device, made of a body-compatible material, used to widen a blood vessel or other body opening

[1]The '303, '120 and '018 patents share the same drawings and essentially the same specification.

(also called a "lumen"), and to maintain the resultant size of the blood vessel or lumen. (Col. 1, lns. 13-17)

b. **"Cell."** An arrangement of structural elements that defines an enclosed space. (Webster's Third New Int'l Dictionary 359 (1993))

c. **"Member having a longitudinal component."** A "member" is a structural element that has its ends at different longitudinal positions with respect to the stent's longitudinal axis. A member's "longitudinal component" is the distance between the longitudinal positions of the first and second ends of the member. (Col. 4, ln. 66 to col. 5, ln. 6)

d. **"Loop."** A structural element that turns back on itself. (Webster's at 1335)

e. **"First loop" and "second loop."** Horizontally-facing (or C-shaped) loops at the cell's two longitudinal ends. (Col. 5, lns. 6-13)

f. **"Disposed between."** Positioned in the space that separates structural elements. (Webster's at 209)

g. **"Disposed generally opposite."** The first and second loops, defined as horizontally-facing structural elements, are positioned across from each other and approximately aligned with each other along the longitudinal axis of the stent. (Col. 5, lns. 6-13)

h. **"Flexible compensating member or flexible link."** A structural element that is flexible with respect to the stent's longitudinal axis and must be aligned along the longitudinal axis of the stent.[2] (Col. 5, lns. 13-31)

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[2]The patents describe the invention as a stent designed to maximize longitudinal flexibility in the unexpanded state (see, e.g., '303 patent, col. 3, lns. 38-45), and to minimize longitudinal foreshortening in the expanded state (see, e.g., '303 patent, col. 1, lns. 52-54; col. 3, ln. 3 to col. 4, ln. 18). In order to accomplish these objectives, the patents describe the structural elements of the stent as being disposed to accommodate movement in two different and compensating directions, a generally vertical direction (see, e.g., '303 patent, col. 2, ln. 63 to col. 3, ln. 2; col. 5, lns. 6-13) and a generally horizontal or longitudinal direction (see, e.g., '303 patent, col. 3, lns. 3-7; col. 5, lns. 13-37). (See also D.I. 138, Ex. 3 at 00174) Further, the patents teach that the structural elements that accommodate movement in the longitudinal direction must be aligned along the longitudinal axis of the stent, as opposed to being diagonal, helical or spiral. (D.I. 137, Ex. 9 at 00059-60; D.I. 138, Ex. 3 at 00175-76) More specifically, the patentee distinguished the Palmaz '417 patent on the following grounds:

> Applicants have also amended Claim 1 to include the limitations of Claim 3 to indicate that the links connect apices of adjacent cells of adjacent rigid segments. This is in contrast to Palmaz '417 and Cardon whose links are spiral-shaped and therefore, do not connect apices of adjacent segments. Instead, they connect the apex of a first cell on one segment with the apex of a second cell (of the second segment) which is shifted from the one which is adjacent to the first cell.

(D.I. 137; Ex. 9 at 00059-60) Based on this language, the court concludes that a flexible compensating member or flexible link must connect adjacent cells, but that neither the prosecution history nor the specification require that the physical connection be made at points directly opposite each other. Nor is there support in the prosecution history or specification for the added limitation suggested by defendants that the flexible compensating members or flexible links run parallel to each other

i. **"Communicating with."** To have a common part, to be connected, join. (Webster's at 460)

j. **"Said first and said second ends disposed a variable longitudinal distance from each other."** The flexible compensating member or flexible link is positioned so that, upon expansion of the stent, the distance between its two ends changes along the stent's longitudinal axis. (Col. 5, lns. 38-62)

k. **"Disposed . . . so as to substantially lessen the foreshortening of said stent upon its expansion."** This limitation encompasses an increase in the distance between the longitudinal positions of the ends of the flexible compensating members or flexible links that is caused by expansion of the stent by a balloon or other mechanical means.[3]

2. **The '303 Patent – Claim 8**

a. **"Area of inflection."** A portion of a stent element that is bent, i.e., a loop. (Webster's at 1160)

3. **The '303 Patent – Claim 12**

(i.e., equidistant at all points) rather than merely lengthwise or in a longitudinal direction. See, e.g., Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., No. 00-1454, 2001 WL 877575, at *11 (Fed. Cir. Aug. 6, 2001).

[3]The court rejects defendants' suggestion that the structures of the stent must be capable of compensating for foreshortening without the aid of a balloon or other delivery device, as the use of a delivery device is clearly contemplated in the patent. (Col. 1, lns. 17-21)

a. **"Uniform cellular structure."** The flexible connected cells of claim 6 have the same structure.

4. **The '120 Patent – Claim 13**

a. **"Meander."** A periodic or repeating pattern of structural elements oriented about a center line. (Col. 2, lns. 61-63) **"First meanders"** and **"second meanders"** identify and differentiate two different patterns. (Col. 2, ln. 61; col. 7, ln. 19)

5. **The '120 Patent – Claim 17**

a. **"Changes in the shape of the loops provides rigidity."** One of the meander patterns must have horizontally-facing loops which change shape upon expansion in order to provide rigidity to the stent. (Col. 4, lns. 28-30; col. 3, lns. 1-7)

6. **The '018 Patent – Claim 35**

a. **"A plurality of first loops and a plurality of second loops."** Two sets of loops.[4]

b. **"Disposed and adapted to cooperate so that upon expansion of said stent said first loops and said second loops**

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[4]Although the phrases "a first loop" and "a second loop" are used in the specification to describe the horizontally-facing (C-shaped) loops at either end of a cell (col. 5, lns. 7-14), the court finds that the phrases "first loops" and "second loops" should not be so limited, a conclusion supported by the fact that the function of minimizing foreshortening requires loops oriented in different directions.

change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded." The two sets of loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. (Col. 4, ln. 58 to col. 5, ln. 63) This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means. (Col. 1, lns. 17-21)

7. **The '018 Patent – Claim 39**

a. **"Said loops adapted so that said stent prior to expansion is substantially uniformly flexible along its longitudinal axis."** The first loops and second loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction, to provide substantially uniform flexibility to the unexpanded stent as one moves longitudinally along the stent.[5] (Col. 3, lns. 39-50; col. 5, lns. 35-39)

b. **"Said first loops and said second loops disposed and adapted to cooperate so that upon the expansion of said stent said first loops and said second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is**

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[5]Contrary to plaintiffs' interpretation, the phrase "substantially uniformly flexible" modifies the word "stent" in this claim, not the word "cells"; the cells must simply be flexible with respect to the longitudinal axis.

expanded." The two sets of loops must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

c. **"Said loops further adapted to impart rigidity."** At least some of the loops must be horizontally-facing loops which change shape to provide rigidity to the stent upon expansion. (Col. 4, lns. 23-26)

8. **The '018 Patent – Claim 47**

a. **"Stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis."** The structural elements of the cells provide longitudinal flexibility such that the flexibility of the stent is substantially uniform as one moves along the longitudinal axis of the stent.

b. **"Apices."** Points at the two longitudinal ends of a cell of a stent. (Webster's at 99)

c. **"Plurality of flexible links."** Structural elements that serve to connect other structural elements but are themselves "disposed apart and generally opposite to one another." (Webster's at 1317; col. 12, lns. 33-35)

d. **"Each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween."** The flexible links are loops.

9. **The '018 Patent – Claim 60**

a. **"Wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded."** The loops disposed on the first meander patterns and the loops disposed on the second meander patterns must be oriented in different directions, one a generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one of the sets of loops in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

10. **The '018 Patent – Claim 63**

a. **"Wherein said stent is adapted so that when it is expanded radially, its overall length remains substantially the same because some elements of said stent grow in said tube's longitudinal direction while some elements of said stent shrink in said tube's longitudinal direction."** The stent must have structural elements oriented in different directions, one a

generally vertical direction and one a generally horizontal or longitudinal direction. This limitation encompasses growth of one set of structural elements in the longitudinal direction that is caused by expansion of the stent by a balloon or other mechanical means.

United States District Judge